EPA REGISTRATION NUMBER 1448-433 – VOL. 1

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:
x Registration
__ Reregistration

(under FtFRA, as amended)

EPA Reg. Number:	Date of Issuance:
1448-433	MAR - 6 2007

Term of Issuance:
Conditional

Name of Pesticide Product:
BUSAN 1215

Name and Address of Registrant (include ZIP Code):

Buckman Laboratories, Inc.
1256 N. McLean Blv.
Memphis, TN 38108

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(C) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Revise the "EPA Registration Number to read, "EPA Reg. No. 1448-433

Signature of Approving Official:

Velma Noble
Product Manager Team-31
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date:
MAR - 6 2007

EPA Form 8570-6

2

Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Velma Noble
Product Manager 31
Regulatory Branch I
Antimicrobials Division (7510P)

Enclosure:

BUSAN 1215

BUSAN is a registered trademark.

A microbiocide for controlling algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products.

ACTIVE INGREDIENT(S)	
Ammonia (total)	7.59%
INERT INGREDIENTS	92.41%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If in Eyes	- Hold eye open and rinse slowly and gently with water for 15-20 minutes. - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. - Call a poison control center or doctor for further treatment advice.
If on Skin, Clothes	- Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for treatment advice.
If Swallowed	- Call poison control center or doctor immediately for treatment advice. - Have person sip a glass of water, if able to swallow. - Do not induce vomiting unless told to do so by the poison control center or doctor. - Do not give anything by mouth to an unconscious person.
If Inhaled	- Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. - Call a poison control center or doctor for further treatment advice.
	HOT LINE NUMBER

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 901-278-0330 or 1-800-BUCKMAN for emergency medical treatment information.

Precautionary Statements

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PULP AND PAPER MILLS: BUSAN 1215 can be used as a microbiocide in the manufacture of paper and paperboard that contacts food.

This product is applied in conjunction with sodium hypochlorite (12.5% al) to form monochloramine, a slower acting less aggressive oxidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.5:1.0 product to 1.0 of ammonia to oxidant, and this ratio is obtained by combining 0.6 fluid ounces of BUSAN 1215 to 1 fluid ounce of sodium hypochlorite (12.5 al). To ensure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water systems through a proper chemical feed skid only by a trained Buckman representative. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

For intermittent treatment mix 0.6 fluid ounces of BUSAN 1215 to 1 fluid ounce of sodium hypochlorite (12.5% a.i.). Apply solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the process water or stock being treated for 5 to 60 minutes every 1 to 6 hours. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

For continuous treatment mix 0.6 fluid ounces of BUSAN 1215 to 1 fluid ounce of sodium hypochlorite (12.5% a.i.). Apply solution at a rate to obtain at least 1 ppm in excess of system oxidant demand (maximum of 5 ppm) measured as total chlorine in the process water or stock being treated on a continuous basis. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

If chloramine is detected in the effluent, it can be neutralized by the addition of sodium meta bisulfite until the chloramine is no longer detected.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAR - 6 2007
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1448-433

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a dry place. Leaking or damaged drums should be placed in overpack drums for disposal. Spills should be absorbed in sawdust or sand and disposed of in a sanitary landfill. Keep container closed when not in use.

PESTICIDE DISPOSAL: Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional office for guidance. Clean equipment and/or dispose of equipment wash water in a manner to avoid contamination of water resources. .

CONTAINER DISPOSAL

PLASTIC: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

METAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Manufactured by
Buckman Laboratories, Inc.
1256 North McLean Blvd.
Memphis, Tennessee 38108, USA
(901) 278-0330 or 1-800-BUCKMAN

EPA Est. No.	1448-TN-1
EPA Reg. No.	1448-
Product Weight	9.59 lbs/gal 1.15kg/l

Net contents are marked on the container

HMIS / NPCA Ratings

Health 1 Flammability 1 Reactivity 0

Last Revision 2/21/2007

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

December 15, 2006

Geraldine E. Edens
McKenna, Long and Aldridge, LLP
1900 K Street, NW
Washington, DC 20006

Dear Ms. Edens:

This responds to your inquiry of August 22, 2006, and subsequent submission dated October 4, 2006, requesting a meeting with FDA to discuss your client's intended use of [redacted] in conjunction with a sodium hypochlorite solution. You state that the [redacted] is combined on-site with the sodium hypochlorite solution to produce monochloramine that you intend to use as an antimicrobial in the manufacture of food-contact pulp and paper. You also submitted data that you believe establishes that no monochloramine residues are expected to become components of food as a result of your proposed use.

As you know from my previous correspondence with Buckman Laboratories, and from our meeting of September 19, 2006, FDA views the reaction product of two substances that are already permitted for use in contact with food to be a unique food additive and therefore subject to regulation as a food additive. Consequently, your proposed use of monochloramine (formed by the reaction of [redacted] and hypochlorite ion) to control microbial growth in the pulp and paper mill should be the subject of an effective food-contact notification whenever residues of the monochloramine are expected to become components of food.

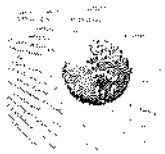
Further, we have reviewed the data and information you submitted regarding the fate of monochloramine in the paper making process. We concur that much of the monochloramine is expected to be consumed by the oxidant demand of the paper manufacturing system, or to hydrolize rather than to become a component of the pulp or paper. Further, any monochloramine that does become incorporated into the paper is expected to volatilize or decompose when the water is removed from the sheet in the drier section of the papermaking process. Therefore, we conclude that monochloramine is not expected to become a component of food as a result of your proposed use as a biocide, at levels not exceeding 5 mg/kg of slurry, in the manufacture of food-contact paper and paperboard.

Inert ingredient information may be entitled to confidential treatment

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Francis Lin, Ph.D.
Director,
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition



Dennis
Edwards/DC/USEPA/US
01/24/2007 09:25 PM

To Drusilla Copeland/DC/USEPA/US@EPA
cc Velma Noble/DC/USEPA/US@EPA
bcc
Subject Re: Fw: File Symbols 1448-UGE/UGG

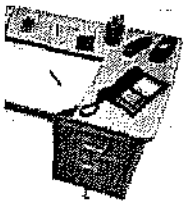
Dru/Velma

Seems like there are a couple of approaches.

1) Register the products as is provided the chemistry data are ok. Then have Buckman submit an amended application to revise the manufacturing process. We would need to discuss whether or not the amendment would be a PRIA.

2) Have Carl submit a revised chemistry package now if they have it. The chemistry package would need to include a new manufacturing process description and probably a 5 batch analysis. We would need to talk to a chemist as to whether other chemistry data are needed. If the new material is identical to the old material then the physical chmical data should not be needed?

Dennis Edwards
Antimicrobials Division
703-308-8087
Drusilla Copeland/DC/USEPA/US



Drusilla
Copeland/DC/USEPA/US
01/24/2007 03:04 PM

To Dennis Edwards/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA
cc
Subject Fw: File Symbols 1448-UGE/UGG

Dennis, I send Carl an email about the phone message and this is what he was asking.
----- Forwarded by Drusilla Copeland/DC/USEPA/US on 01/24/2007 03:02 PM -----

Carl Watson
<cfwatson@buckman.com>
01/24/2007 02:42 PM

To Drusilla Copeland/DC/USEPA/US@EPA
cc "Dennis L. Barbee" <dlbarbee@buckman.com>
Subject RE: File Symbols 1448-UGE/UGG

Talk Dennis would like to registred as is then Came back later with amen to the other part of Chemtrol.
1/29/07

5

"Dennis L. Barbee"
<dlbarbee@buckman.com>
01/02/2007 04:42 PM

To Drusilla Copeland/DC/USEPA/US@EPA
cc 'Carl Watson' <cfwatson@buckman.com>
bcc
Subject RE: EPA File Symbol 1448-UGG and 1448-UGE (BCMW/BSN 1215) registrations

Hi Drusilla,

I am writing this letter in the absence of Carl Watson who has been corresponding with you on the FDA issue regarding EPA file symbols 1448-UGG (Busan 1215) and 1448-UGE (BCMW). As you are aware we have been working via outside counsel and FDA to resolve the FDA issue. Please find attached a copy of the FDA response regarding the use of Busan 1215 in the papermaking process according to the use directions currently pending with EPA.

Carl is on vacation this week and still remains the point of contact for this action. However I would like to request that you contact me at 901.272.8248 when you receive this document. I would like to ensure that it is legible and get a possible timeframe for an EPA response.

Thank you for your assistance and patience in this matter

Kind Regards

Dennis L. Barbee, Ph.D.
Director, Regulatory Affairs
Buckman Laboratories

Busan 1215 FDA Reply.pdf

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] **Registration**
- [ ] **Amendment**
- [x] **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
1448- UGE	Velma Noble	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
BCMW	31	

5. Name and Address of Applicant *(Include ZIP Code)*

Buckman Laboratories, Inc.
1256 N. McLean Blvd
Memphis, TN 38108

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [x] Resubmission in response to Agency letter dated 1/10/05
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional pegals) if necessary. (For section I and Section II.)

1) Submission of corrected pages for Product Chemistry reports; and
2) Resubmission of report to correct pagination entitled:
Supplemental Report: Mammalian Toxicology and
Environmental Fate and Effects (Vol. 1 & II)
Buckman Laboratories, Inc.
Report Date: January 20, 2005

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[x] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
rtification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container	55 & 250 gal, Bulk	[ ]

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carl Watson	Sr. Regulatory Toxicologist	(901) 272-6228

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title	4. Typed Name	5. Date
Carl Watson	Sr. Regulatory Toxicologist	Carl F. Watson, Ph.D.	28 January 2005

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
1448- UGG	Velma Noble	☐ None ☐ Restricted
4. Company/Product (Nemo)	**PM#**	
BCMW / BUSAN 1215	31	

5. Name and Address of Applicant *(Include ZIP Code)*

Buckman Laboratories, Inc.
1256 N. McLean Blvd
Memphis, TN 38108

☐ *Check if this is a new address*

6. Expedited Reveiw. In accprdance with FIFRA Section 3(c)(3)(b)(i), my prpduct is similar or identical in cpmppsitipn and labeling tp:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in rapsonse to Agency letter dated _____
☐ "Me Too" Application.
☑ Other - Explain below.

Explanatipn: Use additional page(s) if necessary. (For section I and Section II.)

New Study submitted in support of registration: BCMW - Manulacture-Use-Only / BUSAN 1215 - End-Use-Product
EPA File Symbol: 1448-UGG

Contact: cfwatson@buckman.com; Fax (901) 272-6256

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packeging	Unit Packaging	Water Soluble Packeging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Spacify) _____
If "Yes" certification must be submitted	If "Yes" Unit Packeging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stencilled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carl Watspn	Sr. Regulatory Toxicplpgist	(901) 272-6228

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Carl F Watsp	Sr. Regulatory Toxicologist	
4. Typed Name	**5. Date**	
Carl F. Watspn, Ph.D.	5 January 2005	10

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Moneger	3. Proposed Classification
1448- UGG / -UGE	Velma Noble	☐ Nane ☐ Restricted
4. Company/Product (Name)	**PM#**	
BCMW / BUSAN 1215	31	

5. Name and Address of Applicant *(Include ZIP Code)*

Buckman Laboratories, Inc.
1256 N. McLean Blvd
Memphis, TN 38108

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☑ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

New Study submitted in support of registrations: BCMW - Manufacture-Use-Only / BUSAN 1215 - End-Use-Product
EPA File Symbols: 1448-UGG and 1448-UGE

Contact: cfwatson@buckman.com; Fax (901) 272-6256

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carl Watson	Sr. Regulatory Toxicologist	(901) 272-6228

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received
Carl F Watson	Sr. Regulatory Toxicologist	(Stamped)
4. Typed Name	**5. Date**	
Carl F. Watson, Ph.D.	6 July 2005	

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
EPA File Symbol 1448-UGE	Velma Noble	☐ None ☐ Restricted
4. Company/Product (Name)	PM#	
BCMW	31	
5. Name and Address of Applicant *(Include ZIP Code)*	6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to:	
Buckman Laboratories, Inc. 1256 N. McLean Blvd Memphis, TN 38108 ☐ *Check if this is a new address*	EPA Reg. No. _____ Product Name _____	

Section - II

☐ Amendment - Explain below.
☑ Resubmission in response to Agency letter dated 5/16/05
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Response to EPA letter dated May 16, 2005; Revised Basic CSF per Agency's comments under the Product Chemistry Review.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carl Watson	Sr. Regulatory Toxicologist	(901) 272-6228

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
Carl Watson	Sr. Regulatory Toxicologist	
4. Typed Name	5. Date	
Carl F. Watson, Ph.D.	12 September 2005	12

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant C

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Friday, March 11, 2005

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 1448-UGG / Busan 1215
DP Barcode: D313227

To: Velma Noble, PM 31/ Drusilla Copeland
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

3/15/05

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Buckman Laboratories, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):		% by wt.
Ammonia		7.59
Other Ingredient(s):		92.41
	Total:	100.00%

1) BACKGROUND: Buckman Laboratories, Inc., has submitted a complete "six-pack" of acute toxicity / irritation studies to support the registration of their product, "Busan 1215". The studies were conducted by Product Safety Laboratories, Inc. The MRID Numbers are 464351-08 through 464351-13.

2) RECOMMENDATIONS: PSB findings are:

a) Each of the six submitted studies is acceptable.

The acute toxicity profile for File Symbol 1448-UGG is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	464351-08	IV	Acceptable
Acute Dermal Toxicity	464351-09	IV	Acceptable
Acute Inhalation Toxicity	464351-10	IV	Acceptable
Primary Eye Irritation	464351-11	IV	Acceptable
Primary Skin Irritation	464351-12	IV	Acceptable
Dermal Sensitization	464351-13	Nonsensitizer	Acceptable

3) LABELING:

a) The signal word is "Caution".
b) Due to the acute toxicity profile (all category IV and nonsensitizer), no precautionary labeling is required.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Product Manager: 31
Reviewer: I. Blackwell
MRID No.: 464351-08
Study Completion Date: 10/7/2004
Lab Study No.: 15282
Testing Laboratory: Product Safety Laboratories, Inc.
Authors: Daniel J. Merkel, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Busan 1215; "clear liquid"
Method: Up and Down Procedure

Species: Sprague-Dawley-derived albino rat
Age: 9-10 weeks
Weight: 180-214 g
Sex: 6 females
Source: Ace Animals, Inc.

Conclusion:

1. **LD_{50} (mg/kg):** **Males =** not tested
Females > 5,000 mg/kg
Combined = not tested
2. **The estimated LD_{50} is greater than 5,000 mg/kg of body weight.**
3. **Toxicity Category**: IV **Classification**: Acceptable

Procedure (Deviations from §81-1): None

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
175	---	0/1	---
550	---	0/1	---
1,750	---	0/1	---
5,000	---	0/3	---

Observations: No abnormalities noted.

Gross Necropsy: No gross abnormalities observed.

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DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 31
MRID No.: 464351-09

Reviewer: Ian Blackwell
Study Completion Date: 10/7/4
Lab Study No.: 15283

Testing Laboratory: Product Safety Laboratories, Inc.
Author: Daniel J. Merkel, B.S.
Quality Assurance (40 CFR §160.12): Included

Test Material: Busan 1215; "clear liquid"

Species: Sprague-Dawley derived albino rat
Weight: males = 292-308g; females = 209-216g **Age**: 9-10 weeks
Source: Ace Animals, Inc.

Summary:

1. **LD_{50} (mg/kg)**: **Males** > 5,000
   Females > 5,000
   Combined > 5,000

2. **The estimated LD_{50} is greater than 5,000 mg/kg b.w.**

3. **Toxicity Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-2): None

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	**Females**	**Combined**
5,000	0/5	0/5	0/10

Observations: No abnormalities were observed.

Gross Necropsy Findings: No gross abnormalities were observed.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

Product Manager: 31
MRID No.: 464351-10

Reviewer: I. Blackwell
Study Completion Date: 10/7/4
Lab Study No.: 15284

Testing Laboratory: Product Safety Laboratories, Inc.
Author: Daniel J. Merkel, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Busan 1215; "clear liquid"
Concentration: Gravimetric-2.08 mg/L; Nominal -157.09 mg/L (nose-only exposure)

Species: Sprague-Dawley derived albino rat
Weight: males = 241-256g; females= 186-214g
Age: 8-9 weeks
Source: Ace Animals, Inc.

Summary:

1. **LC_{50} (mg/L):** **Males** > 2.08 mg/L
   Females > 2.08 mg/L
   Combined > 2.08 mg/L

2. **The estimated LC_{50} is greater than 2.08 mg/L of air.**

3. **MMAD**: 3.05 μm

4. **Toxicity Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-3): None

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.08 mg/L	0/5	0/5	0/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	particles < 4.7 μm
2.08 mg/L	3.05 μm	2.405 μm	66.95%

Chamber Environment	
Chamber Volume	6.7 liters
Airflow	25.4 – 25.8 lpm
Temperature	20-21° C
Relative Humidity	55-57%

Clinical Observations: No abnormalities observed.

Gross Necropsy Findings: No gross abnormalities observed.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 31
MRID No.: 464351-11

Reviewer: Ian Blackwell
Study Completion Date: 10/7/4
Lab Study No.: 15285

Testing Laboratory: Product Safety Laboratories, Inc.
Author(s): Daniel J. Merkel, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Busan 1215; "clear liquid"
Dosage: 0.1 mL
Species: New Zealand albino rabbit
Sex: 3 females
Weight: Not reported **Age**: Young adult
Source: Robinson Services, Inc.

Summary:

1. **Toxicity Category**: IV

2. **Classification**: Acceptable

Procedure (Deviations From §81-4): None

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	---	---	---	---
Iritis	0/3	0/3	0/3	0/3	---	---	---	---
Conjunctivae								
Redness	3/3	0/3	0/3	0/3	---	---	---	---
Chemosis	0/3	0/3	0/3	0/3	---	---	---	---
Discharge	0/3	0/3	0/3	0/3	---	---	---	---

- - - = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 31
MRID No.: 464351-12

Reviewer: Ian Blackwell
Study Completion Date: 10/7/4
Lab Study No.: 15286

Testing Laboratory: Product Safety Laboratories, Inc.
Author: Daniel J. Merkel, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Busan 1215; "clear liquid"
Dosage: 0.5 mL
Species: New Zealand albino rabbit
Age: young adult
Sex: 3 males **Weight**: not reported
Source: Robinson Services, Inc.

Summary:

1. **Toxicity Category**: IV

2. **Classification**: Acceptable

Procedure (Deviations From §81-5): None.

Results: One and twenty-four hours after exposure, 3/3 test animals had very slight erythema with no edema. No other irritation was reported.

Special Comments: None.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 31
MRID No.: 464351-13

Reviewer: Ian Blackwell
Study Completion Date: 10/7/4
Lab Study No.: 15287

Testing Laboratory: Product Safety Laboratories, Inc.
Author: Daniel J. Merkel, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Busan 1215; "clear liquid"
Positive Control Material: o – Hexylcinnamaldehyde (HCA)

Species: Hartley albino guinea pig
Weight: 324-386 g **Age**: young adult
Source: Elm Hill Breeding Labs

Method: Buehler Method

Summary:

1. **This Product is not a dermal sensitizer.**

2. **Classification**: Acceptable

Procedure (Deviation From §81-6): None

Procedure:
Induction: Once each week for three weeks, 0.4 mL of the neat test material was applied. After the six-hour exposure, the test material was removed and the test sites were cleaned. Twenty-seven days after the first induction dose, 0.4 mL of neat test material was applied as a challenge dose. The sites were evaluated 24 and 48 hours after treatment.

Results: Twenty-four hours after induction treatment #1, 8/20 test material-induced animals displayed very faint, usually non-confluent erythema. Twenty-four hours after induction treatment #3, 4/20 test material-induced animals displayed very faint, usually non-confluent erythema.

Twenty-four hours after challenge, 7/20 test material-induced animals displayed very faint, usually non-confluent erythema. At this same point in

the study, 6/10 naïve control animals displayed very faint, usually non-confluent erythema.

Positive control study: Twenty-four hours after induction treatment #1, 6/10 animals displayed faint, usually confluent erythema, and 3/10 displayed faint, confluent erythema. Twenty-four hours after challenge, 7/10 positive control animals displayed faint, usually confluent erythema, and 3/10 displayed faint, confluent erythema. Only 2/5 naïve positive control animals displayed very faint, non-confluent erythema.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of : **Busan 1215**

DP Barcode: **D321671** Reg. No. or File Symbol: **1448-UGG**
Manufacturing-use [ ] End-use Product [**X**]

Active Ingredient Composition:
Ammonia (total).....7.59%

TO: Velma Noble PM 31

FROM: Alex Traska, Chemist 12/12/05
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)
12/13/05

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510 C)

BACKGROUND:

This data submission, in support of the new product registration of **Busan 1215** an end-use microbicide for water systems, was submitted by the registrant, Buckman Laboratories International, Inc.
The product is primarily used in the manufacture of paper and paperboard.

The registrant, in this submission, has provided a twelve-month Storage Stability Study (OPPT 830.6317) and a twelve-month Corrosion Characteristics Study (OPPT 830.6320) for **Busan 1215**.

The following documents were submitted and examined in the chemistry review of this submission: **Busan 1215** Product Chemistry Data for Guidelines 830.6317 and 830.6320 dated June 30, 2005under MRID # 465866-01, Basic CSF for **Busan 1215** dated December 21, 2004 and product label for **Busan 1215** dated 12/21/04.

FINDINGS:

1. The one-year Storage Stability and Corrosion Characteristics studies performed by EcoLab, Inc. and dated June 30, 2005 were GLP compliant and acceptable from a technical standpoint. After one-year of ambient storage the active ingredient concentration was within certified limits and no deterioration to the product package (opaque HDPE) was noted.

RECOMMENDATIONS:

These study submissions, covering the one-year Storage Stability and Corrosion Characteristics studies for **Busan 1215**, are accepted.

12/12/05 AT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 9, 2005

Memorandum

Subject: Hazard Assessment for Ammonia and Monochloroamine

Active Ingredient: Ammonia
PC Code 128824

DP Barcode: D313637

From: Deborah Smegal, MPH, Toxicologist
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Through: Norm Cook, Branch Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

To: Drusilla Copeland
Regulatory Management Branch I
Antimicrobials Division (7510C)

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1.0 BACKGROUND

The Agency was requested to review a new use for ammonia for use in food-contact pulp/paper. The registrant proposes to mix their product BCMW/BUSAN 1215, which contains dilute solutions of ammonia, with sodium hypochlorite (12.5%) to form monochloramine on pulp/paper. Thus, this hazard assessment will evaluate both potential occupational exposure to ammonia and potential dietary exposures to monochloramine. Therefore, the toxicity profile for ammonia focuses on the hazard associated with dermal and inhalation exposures, while the toxicity profile for monochloramine focuses on the hazard associated with oral exposures.

2.0 HAZARD ASSESSMENT

2.1 Acute Toxicity of BUSAN 1215

The acute toxicity data for the product BUSAN 1215 containing 7.59% are acceptable. All of the acute toxicity studies for BUSAN 1215 are listed in category IV, and it is a non-sensitizer. The acute toxicity data on the BUSAN 1215 is summarized below in Table 1.

Table 1. Acute Toxicity Data on Busan 1215

Guideline No./ Study Type	MRID No.	Results	Toxicity Category
870.1100 Acute oral toxicity	46435108	$LD_{50} > 5000$ mg/kg	IV
870.1200 Acute dermal toxicity	46435109	$LD_{50} > 5000$ mg/kg	IV
870.1300 Acute inhalation toxicity	46435110	$LC50 \geq 2.08$ mg/L (4-hr)	IV
870.2400 Acute eye irritation	46435111	Minimally irritating (rabbit) Irritation cleared within 48 hours	IV
870.2500 Acute dermal irritation	46435112	Slightly irritating	IV
870.2600 Skin sensitization	46435113	Not a skin sensitizer (guinea pig)	

2.2. Ammonia Toxicity Profile

Ammonia is an essential mammalian metabolite for DNA, RNA and protein synthesis and is necessary for maintaining acid-base balance. It is produced and used endogenously in all mammalian species. Ammonia is excreted primarily as urea and urinary ammonium compounds through the kidneys (ATSDR 2004).

Acute. Ammonia is a corrosive substance and the main toxic effects are restricted to the sites of direct contact with ammonia (i.e., skin, eyes, respiratory tract, mouth, and digestive tract). It is an upper respiratory irritant in humans. The acute toxicity of gaseous ammonia is generally considered the effect of the chemical reactivity producing an extremely sharp, irritating odor

causing eye, skin, and respiratory irritation. At concentrations exceeding 50 ppm, immediate nose and throat irritation is experienced (ATSDR 2004). Immediate lethality may occur at concentrations in excess of 5,000 ppm; however, the acute lethal exposure concentration depends on the exposure duration (ATSDR 2004).

The skin is extremely sensitive to airborne ammonia or ammonia dissolved in water. Dermal exposures to liquid ammonia or concentrated solutions and/or ammonia gas are frequently occupationally related and produce cutaneous burns, blisters, and lesions of varying degrees of severity. The topical damage caused by ammonia is probably due mainly to its reactivity and irritation properties. Its high water solubility allows it to dissolve in moisture on these surfaces, react with fatty substances, be absorbed into deeper layers, and inflict extensive damage. The severity of the damage is proportional to the concentration and duration of exposure; flushing with water immediately after contact alleviates or prevents effects (ATSDR 2004).

Ingestion of concentrated ammonium solutions may produce severe burns and hemorrhage of the upper gastrointestinal tract (ATSDR 2004).

Subchronic. Ammonia causes adverse respiratory effects in animals following inhalation exposure. Below are summaries of several inhalation toxicity studies presented in USEPA (2005a).

Broderson et al. (1976) exposed groups of F344 rats (6/sex/dose) continuously to 25, 50, 150 or 250 ppm ammonia (HEC = 1.9, 3.7, 11.2 or 18.6 mg/cu.m, respectively) for 7 days prior to inoculation with Mycoplasma pulmonis and from 28-42 days following M. pulmonis exposure. Each treatment group had a corresponding control group exposed only to background ammonia and inoculated with M. pulmonis in order to produce murine respiratory mycoplasmosis (MRM). The following parameters were used to assess toxicity: clinical observations and histopathological examination of nasal passages, middle ear, trachea, lungs, liver and kidneys. All levels of ammonia, whether produced naturally or derived from a purified source, significantly increased the severity of rhinitis, otitis media, tracheitis and pneumonia characteristic of M. pulmonis. Furthermore, there was a significant concentration response between observed respiratory lesions and increasing environmental ammonia concentration for gross and microscopic lesions. All lesions observed were characteristic of MRM. Gross bronchiectasis and/or pulmonary abscesses and the extent of gross atelectasis and consolidation was consistently more prevalent in exposed animals at all concentrations than in their corresponding controls. The severity of the microscopic lesions in the nasal passages, middle ears, tracheas and lungs was significantly greater in all exposed groups compared with controls. Increasing ammonia concentration was not associated with an increasing frequency of M. pulmonis isolations. Additionally, rats not exposed to M. pulmonis and exposed to ammonia at 250 ppm developed nasal lesions (epithelial thickening and epithelial hyperplasia) unlike those observed in inoculated rats. Based upon these data in M. pulmonis exposed rats, a LOAEL(HEC) of 1.9 mg/cu.m was identified.

Gamble and Clough (1976) whole-body exposed female Porton rats to ammonia concentrations of 200 (+/- 50) ppm for 4, 8 or 12 days or 435 (+/- 135) ppm for 7 days. Duration of exposure was not otherwise specified. The total number of animals was 16, but the apportionment into

exposure groups was not provided. Hyperplasia of the tracheal epithelium was shown to be concentration- and time-dependent. At 4 days of exposure to 200 ppm, the epithelium had changed to transitional-stratified and by 8 days there was gross change: disappearance of cilia and stratification increasing to folds forming on the luminal surface. A mucilaginous exudate was also evident with a slight increase in submucosal cellularity. At 12 days at the 200 ppm concentration, the epithelialization had increased in thickness. Rats exposed for 7 days to 435 ppm showed acute inflammatory reactions with infiltration of neutrophils, large mononucleated cells, monocytes and immature fibroblasts in the trachea. Evidence of necrotic changes at the luminal surface included pyknotic nuclei and karyorrhectic cells.

Groups of 10 guinea pigs and 20 Swiss albino mice were exposed continuously to an ammonia-air concentration of 20 ppm (13.9 mg/cu.m) for up to 6 weeks. A separate group of six guinea pigs was similarly exposed to an ammonia concentration of 50 ppm (35 mg/cu.m) for 6 weeks, and a group of 21 Leghorn chickens was exposed to a 20 ppm concentration for up to 12 weeks. Controls (number not specified) were maintained under identical conditions, except for the ammonia. Smaller groups of chickens were exposed continually to either 200 ppm for up to 3 weeks or 1000 ppm for up to 2 weeks. The effects of ammonia were found to be both time- and concentration-dependent. While no effects were observed in guinea pigs, mice, or chickens sacrificed after 1, 2, 3 or 4 weeks of exposure at 20 ppm, darkening/reddening, edema, congestion, and hemorrhage were seen in the lungs of all three species at sacrifice after 6 weeks of exposure at that concentration. In guinea pigs exposed to 50 ppm ammonia for 6 weeks, grossly enlarged and congested spleens, congested livers and lungs, and pulmonary edema were seen. In chickens exposed to 200 ppm for 17-21 days, liver congestion and slight clouding of the cornea were observed in addition to those effects observed in the chickens exposed to 20 ppm ammonia for 6 weeks. At 1000 ppm, the same effects, in addition to congestion of the spleen, were seen in chickens after just 2 weeks of exposure, and corneal opacities developed within just 8 days of exposure. In a second series of experiments, it was found that a 72-hour exposure to 20 ppm ammonia significantly increased the infection rate of chickens subsequently exposed to an aerosol of Newcastle disease virus, while the same effect was observed in just 48 hours in chickens exposed to 50 ppm. Changes in gross and micropathology did not accompany the change in disease rate (Anderson et al., 1964).

Guinea pigs were exposed to 0 or 170 ppm (118 mg/cu.m) 6 hours/day, 5 days/week for up to 18 weeks. No adverse effects were observed in animals exposed to ammonia for 6-12 weeks (HEC=21 mg/cu.m). Mild changes in the spleen, kidney suprarenal glands and livers were observed (HEC=19 mg/cu.m) in guinea pigs exposed for 18 weeks. No effects on the lungs were observed. The upper respiratory tract was not examined (Weatherby, 1952).

Swiss-Webster mice (16-24/group) were exposed to 0 or 305 ppm ammonia (212 mg/cu.m) 6 hours/day for 5 days. Nasal lesions were observed at 212 mg/cu.m which when dose duration adjusted for the RGDR, equals a LOAEL(HEC) of 4.5 mg/cu.m (Buckley et al., 1984).

Continuous exposure of rats to ammonia at 0, 40, 127, 262, 455 or 470 mg/cu.m for a minimum of 90 days (114 days for the 40 mg/cu.m group) was conducted in male and female Sprague-Dawley and Long-Evans rats. A LOAEL of 262 mg/cu.m (HEC=28 mg/cu.m) was determined based upon nasal discharge in 25% of the rats, and nonspecific circulatory and degenerative

changes in the lungs and kidneys that were difficult to relate specifically to ammonia inhalation. A frank-effect-level of 455 mg/cu.m (HEC=48.7 mg/cu.m) was observed due to high mortality in the rats (90-98%). Nasal passages were not histologically examined (Coon et al., 1970).

Duroc pigs were exposed to ammonia concentrations of 10, 50, 100 and 150 ppm. Exposure to ammonia significantly decreased both food intake and body weight gain. Higher concentrations caused nasal, lacrimal and mouth secretions, which became less severe over time. No treatment-related gross or microscopic changes were observed in the bronchi, lungs or turbinates at necropsy (Stombaugh et al., 1969).

Various animal species were exposed to 0, 155 and 770 mg/cu.m for 8 hours/day, 5 days/week for 30 exposures (rats, guinea pigs, rabbits, dogs and monkeys). The LOAEL for lung inflammation is 770 mg/cu.m for rats (HEC=82.4 mg/cu.m) and guinea pigs. Ocular and nasal irritation was observed at 770 mg/cu.m in rabbits and dogs. The upper respiratory tract was not examined (Coon et al., 1970).

Developmental/Reproductive. No developmental or reproductive studies have been conducted by the registrant for ammonia.

Neurotoxicity. No neurotoxicity studies have been conducted by the registrant. Studies in the scientific literature indicate that neurological effects have been observed in humans following inhalation and dermal exposure. These effects have been limited to blurred vision, most likely due to direct contact, but more severe exposures, which result in significant elevation of blood ammonia levels (hyperammonemia) can result in diffuse nonspecific encepthalopathy, muscle weakness, decreased deep tendon reflexes and loss of consciousness (ATSDR 2004).

Cerebral edema and herniation and intracranial hypertension have been noted in animal models of hyperammonemia. The mechanism of ammonia-induced encephalopathies has not been definitively elucidated. It is thought to involve the alteration of glutamate metabolism in the brain with resultant increased activation of N-methyl-D-aspartate (NMDA) receptors, which causes decreased protein kinase C-mediated phosphorylation of Na+/K+ ATPase, and depletion of ATP. This reduced ATP level may be involved in ammonia-induced coma and death. A disruption in neurotransmission has also been suggested by alteration of brain tubulin, which is an essential component of the axonal transport system (ATSDR 2004).

Chronic. Chronic occupational exposure to low levels of airborne ammonia (< 25 ppm) had little effect on pulmonary function or odor sensitivity in workers at some factories, but studies of farmers exposed to ammonia and other pollutants in livestock buildings indicated an association between exposure to pollutants, including ammonia, and an increase in respiratory symptoms and/or decrease in lung function parameters. The contribution of ammonia to these respiratory symptoms is unclear (ATSDR 2004).

USEPA (2005a) established an inhalation reference concentration (RfC) based on both an epidemiological study and an animal toxicity study to be protective of respiratory effects. A no-observable-adverse effect level (NOAEL) of 6.3 mg/m^3 (9.2 ppm) from an occupational study

was combined with a lowest observable adverse effect level (LOAEL) of 17.5 mg/m^3 (25 ppm), which has a human equivalent concentration (HEC) of 1.9 mg/m^3, for respiratory effects in a rat subchronic inhalation study. The Agency acknowledges that there is a lack of adequate reproductive and developmental toxicology studies for ammonia in the IRIS record (USEPA 2005a), and applied an additional 3X factor to account for these deficiencies. Based on the proposed use pattern, BCMW/BUSAN 1215 containing dilute solutions of ammonia is mixed with sodium hypochlorite (12.5%) to form monochloramine in pulp/paper. Because there is no concern for potential dietary exposure to ammonia for this proposed use pattern, it is not necessary to consider the FQPA safety factor for ammonia. However, the Agency believes the FQPA factor should be considered for the potential dietary exposures to monochloramine (see below).

Mutagenicity/Carcinogenicity. There is no evidence that ammonia causes cancer. Ammonia has not been classified for carcinogenic effects by EPA, the Department of Health and Human Services (DHHS), or the International Agency for Research on Cancer (IARC) (ATSDR 2004).

There are a few studies on the genotoxicity of ammonia. Overall, these studies suggest that ammonia and ammonia ion may have clastogenic and mutagenic properties. One study evaluated blood samples from 22 workers exposed to ammonia in a fertilizer factory and 42 control workers not exposed, and found an increased frequency of chromosomal aberrations (CAs) and sister chromatid exchanges (SCEs), increased mitotic index (MI) and increased frequency of CAs and SCEs with increasing length of exposure (Yadav and Kaushik 1997 as cited in ATSDR 2004). An increased frequency of micronuclei compared to controls was noted in mice administered ammonium intraperitoneally (Yadav and Kaushik 1997 as cited in ATSDR 2004). There were positive effects in a reverse mutation test in E. coli, but only in treatments using toxic levels of NH_4+ (98% lethality). Another study found slight mutagenic activity in *Drosophila* following exposure to ammonia gas, but at toxic levels (survival after treatment was <2%). *In vitro* tests of chick fibroblast cells showed that buffered ammonia-ammonium chloride solutions can induce clumping of chromosomes, inhibit spindle formation and result in polyploidy (Rosenfeld 1932 as cited in ATSDR 2004). Reduced cell division was noted in mouse fibroblasts cultured in media to which ammonia and ammonium chloride were added (Visek et al. 1972 as cited in ATSDR 2004).

2.3 Monochloramine Toxicity Profile

Developmental/reproductive. The developmental and reproductive toxicity of monochloramine has been examined in rats, but with suboptimal studies. However, due to the chemical relationship between monochloramine and chlorine, the Agency believes that the reproductive and developmental studies for chlorine may be used to satisfy these data gaps for monochloramine. The available studies do not indicate concerns for increased sensitivity of the fetus or offspring. Thus, the Agency believes it is appropriate to reduce the FQPA factor to 1X for monochloramine. Below are summaries of reproductive and developmental studies.

In a reproductive study by Carlton et al. (1986), chloramine was administered by gavage in deionized water at doses of 0, 2.5, 5.0 and 10 mg chloramine/kg/day to male (12/dose group) and female (24/dose group) Long Evans rats for a total of 66-76 days. Males were treated for 56 days

and females for 14 days prior to mating. Dosing continued during the 10-day mating period and afterwards females were dosed with chloramine daily during gestation and lactation. Males were necropsied at the end of the mating period. Dams and some offspring were necropsied at 21 days after birth. Other offspring were dosed with chloramine after weaning until they were 28-40 days old. No statistical differences were observed between control and exposed rats in fertility, viability, litter size, day of eye opening or average day of vaginal patency. There were no alterations in sperm count, direct progressive sperm movement, percent mobility or sperm morphology in adult males. Weights of male and female reproductive organs were not significantly different among control and test groups, and there were no significant morbid anatomic changes evident on tissue examination. There were no signs of toxicity, changes in blood counts, or effects on body weight in adult rats of either sex at any dose level. The mean weight of the pups was not affected by chloramine treatment. A NOAEL of 10 mg/kg-day for reproductive effects can be defined from this study.

Abdel-Rahman et al. (1982) administered monochloramine in the drinking water to female Sprague-Dawley rats (6/dose group) at 0, 1, 10 and 100 mg/L for 2.5 months prior to and throughout gestation. By using body weights provided by the investigators and a reference water consumption value (U.S. EPA, 1987), the intake of monochloramine was estimated to be to 0, 0.15, 1.5 and 15 mg monochloramine/kg/day. Treatment with monochloramine did not increase the number of fetal resorptions or affect fetal weight. In addition, monochloramine did not induce soft-tissue anomalies or skeletal malformations. A developmental NOAEL of 15 mg monochloramine/kg/day is provided by this study, although confidence is low due to the small number of animals exposed.

Chronic. The long-term effects of chloraminated water were examined in rats and mice (NTP 1992). In both species, there were no statistically significant findings attributable to chemical exposure at the highest dose tested of 200 ppm chloramine, or 9.5 mg chloramine/kg/day for rats and 17.2 mg chloramine/kg/day for mice. The NOAEL of 9.5 mg chloramine/kg/day in rats is chosen as the basis for the chronic oral RfD by USEPA (2005b). Although a higher NOAEL in the study of 17.2 mg/kg-day is found for mice, rats may be the more sensitive species since doses between 9.5 and 17.2 mg/kg-day were not tested in rats.

Mutagenicity/Carcinogenicity. Monochloramine is not classifiable as to human carcinogenicity (Group D) based on inadequate human data and equivocal evidence of carcinogenicity from animal bioassays. A two-year bioassay showed marginal increase in mononuclear cell leukemia in female F344/N rats. No evidence of carcinogenic activity was reported in male rats or in male or female B6C3F1 mice. Genotoxcity studies, both in vitro and in vivo, gave negative results (USEPA 2005b).

3.0 TOXICITY ENDPOINT SELECTION

Tables 2 and 3 present a summary of the recommended toxicity endpoints for ammonia and monochloramine, respectively to be used in the risk assessment.

A. Occupational Exposure to Ammonia

A.1 Dermal Exposure (All durations).

No endpoint was selected because the labels will specify the use of gloves, full body clothing and eye protection. Thus, there is no potential for dermal exposure.

A.2 Inhalation Exposure (All durations)

Study Selected: Holness et al. (1989) epidemiological study of workers

Executive Summary: Holness et al. (1989) investigated production workers exposed to ammonia in a soda ash facility. All of the available 64 production workers were invited to participate and 82% agreed to be evaluated. The control group consisted of 31 other plant workers from stores and office areas of the plant without previous exposure to ammonia. The mean age of the workers was 38.9 years and duration of exposure was 12.2 years. Weight was the only statistically significant difference in demographics found after comparing height, weight, years worked, % smokers and pack-years smoked. The mean TWA ammonia exposures based on personal sampling over one work shift (average sample collection 8.4 hours) of the exposed and control groups were 9.2 ppm (6.4 mg/cu.m) and 0.3 ppm (0.21 mg/cu.m), respectively.

A questionnaire was administered to obtain information on exposure and work histories and to determine eye, skin and respiratory symptomatology (based on the American Thoracic Society [ATS] questionnaire [Ferris, 1978]). Spirometry (FVC, FEV-1, FEF50 and FEF75) was performed according to ATS criteria at the beginning and end of each work shift on the first workday of the week (day 1) and the last workday of the week (day 2). Differences in reported symptoms and lung function between groups were evaluated using the actual values and with age, height and pack-years smoked as covariates in linear regression analysis. Baseline lung function results were expressed as percent of predicted values calculated from Crapo et al. (1981) for FVC and FEV-1 and from Lapp and Hyatt (1967) for FEF50 and FEF75.

No statistical difference in the prevalence of the reporting symptoms was evident between the exposed and control groups, although workers reported that exposure at the plant had aggravated specific symptoms including coughing, wheezing, nasal complaints, eye irritation, throat discomfort and skin problems. The percentage of exposed workers reporting hay fever or familial history of hay fever was significantly less than controls, suggesting possible self-selection of atopic individuals out of this work force. The atopic status of the worker and control groups was not determined by skin prick tests to common aeroallergens. Furthermore, the workers complained that their symptomatology was exacerbated even though there was no statistical difference between groups. Since the study was cross-sectional in design with a small population, it is possible that selection bias may have occurred.

Baseline lung functions (based on the best spirometry values obtained during the four testing sessions) were similar in the exposed and control groups. No changes in lung function were demonstrated over either work shift (days 1 or 2) or over the workweek in the exposed group

compared with controls. No relationship was demonstrated between chronic ammonia exposure and baseline lung function changes either in terms of the level or duration of exposure, probably due to lack of adequate exposure data for categorizing exposures and thus precluding development of a meaningful index accounting for both level and length of exposure.

Based on the lack of subjective symptomatology and changes in spirometry, this study establishes a free-standing TWA NOAEL of 9.2 ppm (6.4 mg/cu.m). Adjustment for the TWA occupational scenario results in a NOAEL(HEC) of 2.3 mg/cu.m.

Dose and Endpoint for Risk Assessment: The 8 hour-TWA NOAEL of 9.2 ppm (6.4 mg/m^3) was selected based on lack of evidence of decreased pulmonary function or changes in subjective syptomatology in the occupational study (Holness et al. 1989). The 24-hour adjusted NOAEL is 2.3 mg/m^3. This 24-hour NOAEL is the basis of the Agency's inhalation reference concentration (RfC) presented on the Integrated Risk Information System (IRIS) and represents Agency consensus. Since ammonia is a respiratory irritant, the Agency believes that the irritation potential would limit exposure. See USEPA (2005a) for more details on the inhalation RfC and a discussion of other supporting toxicity studies.

Margin of Exposure for Occupational Exposure: For all durations, a MOE of 30 is adequate. An uncertainty factor of 10 is used to allow for the protection of sensitive individuals (intra-species extrapolation). Because it is based on a human epidemiological study, no inter-species safety factor is required. A factor of 3 was used to account for several data base deficiencies including the lack of chronic data, and the lack of reproductive and developmental toxicology studies. This factor is not larger than 3, however, since studies in rats (Schaerdel et al., 1983) have shown no increases in blood ammonia levels at exposures 32 ppm and only minimal increases at 300-1000 ppm, suggesting that no significant distribution is likely to occur at the human equivalent concentration (HEC) level calculated.

B. Dietary Exposure to Monochloroamine

B.1 Acute Reference Dose (RfD)

An acute RfD was not identified because there were no effects attributable to a single dose.

B.2 Chronic Reference Dose (RfD)

Study Selected: Rat Chronic Oral Study (National Toxicology Program 1992)

Executive Summary. The long-term effects of chloraminated water were examined in F344/N rats and B6C3F1 mice (NTP, 1992). Groups of rats (70/sex/dose) and mice (70/sex/dose) were administered chloraminated drinking water at 0 (controls), 50, 100 or 200 ppm for 103-104 weeks. Based on body weight and water consumption data provided in the study, the intake of

chloramine was 0, 2.6, 4.8 and 8.7 mg/kg-day for male rats; 0, 3.4, 5.3 and 9.5 mg/kg-day for female rats. Consumption of chloramine in mice was 0, 5.0, 8.9 and 15.9 mg/kg-day for males; and 0, 4.9, 9.0 and 17.2 mg/kg-day for females. Interim sacrifices (10/sex/dose) were conducted at weeks 14 and 66. At these times, a complete hematologic examination and necropsy were performed in all sacrificed animals. In addition, histopathologic examination was conducted in all control and high-dose animals. At the completion of the study, a complete histopathologic evaluation was performed in all animals. A dose-related decrease in water consumption was evident in rats throughout the study; food consumption was not affected by treatment. Mean body weights of high-dose male and female rats were lower than their respective controls. However, mean body weights were within 10% of controls until week 97 for females and week 101 for males. Decreases ($p<0.05$) in liver and kidney weight in the high-dose males and increases ($p<0.05$) in the brain- and kidney-to-body weight ratios in the high- dose rats (both sexes) were related to lower body weights in these groups and were not considered toxicologically significant. Results from pathologic evaluation at weeks 14 and 66 were unremarkable. The authors found no clinical changes attributable to consumption of chloraminated water. There were no non-neoplastic lesions after the 2-year treatment with chloraminated water. A NOAEL for rats of 200 ppm chloramine, or 9.5 mg chloramine/kg/day, can be defined in this study.

In treated mice, water consumption throughout the study was also decreased in a dose-related manner. Food consumption was slightly lower in high-dose females compared with controls. Body weights of treated male and female mice were lower than in controls; the effect was dose-related. On the average, body weights of high-dose males were 10-22% lower than controls after week 37; those of high-dose females were 10-35% lower than controls after week 8. Mice exhibited no adverse clinical signs attributed to treatment with chloramine. Survival rates between treated and control mice were not significantly different. Interim evaluations revealed no biologically significant differences in organ weights or in relative organ weights. There were occasional statistically significant differences, such as decreases in liver weights and increases in brain- and kidney-to-body weight ratios in high-dose male and female mice, but these were attributed to the lower body weights and were not considered toxicologically significant. Results from hematology tests, and gross or microscopic examination of tissues and organs were unremarkable. The 2-year evaluation revealed no non-neoplastic lesions attributable to chloramine treatment. The concentration of 200 ppm chloramine, or 17.2 mg chloramine/kg/day is considered a NOAEL for mice in this study.

Dose and Endpoint for Risk Assessment: The NOAEL of 9.5 mg/kg/day (200 ppm) was selected based on no observable adverse effects in the rat chronic oral study (NTP 1992). This NOAEL is the basis of the Agency's oral reference dose (RfD) presented on the Integrated Risk Information System (IRIS) and represents Agency consensus. Although a higher NOAEL in the study of 17.2 mg/kg-day is found for mice, rats may be the more sensitive species since doses between 9.5 and 17.2 mg/kg-day were not tested in rats. Significant decreased weight gain in subchronic rat studies, such as Daniel et al. (1990), at 200 ppm was considered a consequence of decreased water consumption associated with taste aversion.

Uncertainty factors: 100 (10x interspecies extrapolation, 10x intraspecies variation, 1x FQPA safety factor). The FQPA safety factor is reduced to 1X for monochloramine because data from

existing reproductive and developmental studies across chemical class (monochloramine and chlorine) provide sufficient confidence that the reproductive and developmental issues have been addressed. Although the studies with chlorine are marginal in quality, they do give an indication that adverse effects from monochloramine are not likely to occur (see Section 2.3).

Comments about Study/Endpoint Uncertainty Factor: This study represents the best available data to assess chronic toxicity.

$$\text{Chronic RfD} = \frac{\text{9.5 mg/kg/day (NOAEL)}}{\text{100 (UF)}} = \textbf{0.1 mg/kg/day}$$

C. Classification of Carcinogenic Potential

Ammonia: There is no evidence that ammonia causes cancer. Ammonia has not been classified for carcinogenic effects by EPA, the Department of Health and Human Services (DHHS), or the International Agency for Research on Cancer (IARC) (ATSDR 2004).

Monochloramine: Monochloramine is not classifiable as to human carcinogenicity (Group D) based on inadequate human data and equivocal evidence of carcinogenicity from animal bioassays. A two-year bioassay showed marginal increase in mononuclear cell leukemia in female F344/N rats. No evidence of carcinogenic activity was reported in male rats or in male or female B6C3F1 mice. Genotoxcity studies, both in vitro and in vivo, gave negative results (USEPA 2005b).

4.0 FQPA CONSIDERATIONS

4.1 Special Sensitivity to Infants and Children

Ammonia: The Agency acknowledges that there is a lack of adequate reproductive and developmental toxicology studies for ammonia in the IRIS record (USEPA 2005a). However, based on the proposed use pattern, BCMW/BUSAN 1215 containing dilute solutions of ammonia is mixed with sodium hypochlorite (12.5%) to form monochloramine in pulp/paper. Because there is no concern for potential dietary exposure to ammonia for this proposed use pattern, it is not necessary to consider the FQPA safety factor for ammonia. However, the Agency believes the FQPA factor should be considered for the potential dietary exposures to monochloramine.

Monochloramine: As noted in the USEPA (2005b) IRIS record, the developmental and reproductive toxicity of monochloramine has been examined in rats, but with suboptimal studies. These studies are summarized below. However, due to the chemical relationship

between monochloramine and chlorine (U.S. EPA, 1992), reproductive and developmental studies for chlorine (Druckrey, 1968; McKinney et al., 1976; Chernoff et al., 1979; Staples et al., 1979; Meier et al., 1985) may be used to satisfy these data gaps for monochloramine. The available studies do not indicate concerns for increased sensitivity of the fetus or offspring. Thus, the Agency believes it is appropriate to reduce the FQPA factor to 1X for monochloramine.

Tale 2
Summary of Toxicological Dose and Endpoints for Ammonia [1]

Exposure Scenario	Dose Used in Risk Assessment, UF	Level of Concern for Risk Assessment (LOC) for Occupational Risk	Study and Toxicological Effects
Dermal (all durations) (Occupational)	Labels will specify the use of gloves, full body clothing and eye protection.		
Inhalation (all durations) (Occupational)	NOAEL= 6.3 mg/m^3 (9.2 ppm) 8-hr TWA NOAEL(HEC)= 2.3 mg/m^3 (24 hour concentration)	LOC for MOE = 30 (Occupational)	Occupational Study (Holness et al. 1989) LOAEL= none See IRIS record (USEPA 2005a) for more detailed discussion.

[1] *UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, LOC=level of concern , MOE = margin of exposure, HEC= human equivalent concentration*

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Schaerdel, A.D., W.J. White, C.M. Lane, B.H. Dvorchik and K. Bohner. 1983. Localized and systemic effects of environmental ammonia in rats. Lab. Anim. Sci. 33(1): 40-45.

Staples, R.E., W.C. Worthy and T.A. Marks. 1979. Influence of drinking water-tap versus purified on embryo development in mice. Teratology. 19: 237-244.

Stombaugh, D.P., H.S. Teague and W.L. Roller. 1969. Effects of atmospheric ammonia on the pig. J. Animal Sci. 28: 844-847.

U.S. EPA. 1992. Drinking Water Criteria Document for Chloramines. Prepared by the Environmental Criteria and Assessment Office, Office of Health and Environmental Assessment, Cincinnati, OH for the Office of Science and Technology, Office of Water, Washington, DC. (External Review Draft)

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DP #: (313226) Decision #: 352404

DATA PACKAGE BEAN SHEET

Date: 14-Feb-2005

* * * Registration Information * * *

Registration: 1448-UGG - BUSAN 1215 - End-use Products

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# CM-2 308B

Risk Manager Reviewer: Drusilla Copeland DCOPELAN

Sent Date: _____ Calculated Due Date: ~~18-Mar-2006~~ April 8, 2006 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A46.0) NEW USE;WITH EXEMPTION;NEW FOOD USE;

Ingredients: _____

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 14-Feb-2005 Due Back: _____

DP Ingredient: _____

DP Title: _____

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: _____

Assigned To		Date In	Date Out
Organization:	AD / PSB	2/14/05	
Team Name:	CTT	2/14/05	
Reviewer Name:	Alex	2/15/05	
Contractor Name:			

Administrative Due Date: 10-Jun-2005

Negotiated Due Date: 3/8/06

Projected Completion Date: 2/24/06

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Please review the attach chemistry data on ammonia
MRID# 46435102,46435114,46435104. Rejected physical/chemical data will be attached shortly.

464351-00

Buckman
LABORATORIES

BUCKMAN LABORATORIES INTERNATIONAL, INC.

1256 NORTH McLEAN BLVD.
MEMPHIS, TN 38108-1241 U.S.A.
TELEPHONE (901) 278-0330
FAX (901) 276-5343
www.buckman.com
e-mail: knetix@buckman.com

Via Federal Express

December 21, 2004

US Environmental Protection Agency
Document Processing Desk (New Registration)
Office of Pesticide Programs, Antimicrobial Division (PM 31)
Crystal Mall 2, Room 266A
1801 S. Bell Street
Arlington, VA 22202

Re: BCMW / BUSAN 1215 - Application for a New Pesticides

Enclosed please find an application for a new product registration for Buckman Laboratories, Inc. product: BCMW - MUP and BUSAN 1215 - EUP). Enclosed you will find the following information to support this application:

- Two (2) Applications under PRIA, one for each Pesticide Registration (MUP/EUP)
- Three (3) copies of each product Confidential Statement of Formula
- Two (2) Certifications with Respect to Citation of Data, one for each product.
- Two (2) Data Requirement Listings (Data Matrix)
- One (1) copy of Data Waiver
- Five (5) Copies of the Proposed Labeling for each product.
- Three (3) Copies of all Required Toxicology Studies

If you have any questions or require any additional information regarding this application, please feel free to contact me.

Sincerely,
BUCKMAN LABORATORIES INTERNATIONAL, INC.

Carl F. Watson, Ph.D.
Sr. Regulatory Toxicologist

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter:

Buckman Laboratories, Inc.
1256 N. McLean Blvd.
Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

Data to Support New Registration:
Busan 1215 – End Use Product

3. Transmittal Date: 21 December 2004

4. List of Submitted Studies:

Vol. 1: Product Chemistry for BUSAN 1215:
Product Identity, Composition and Analysis
Buckman Laboratories, Inc.
Report Date: December 21, 2004

Guideline Number: Series 61 & 62 (OPPTS 830 Series)

MRID No: _____

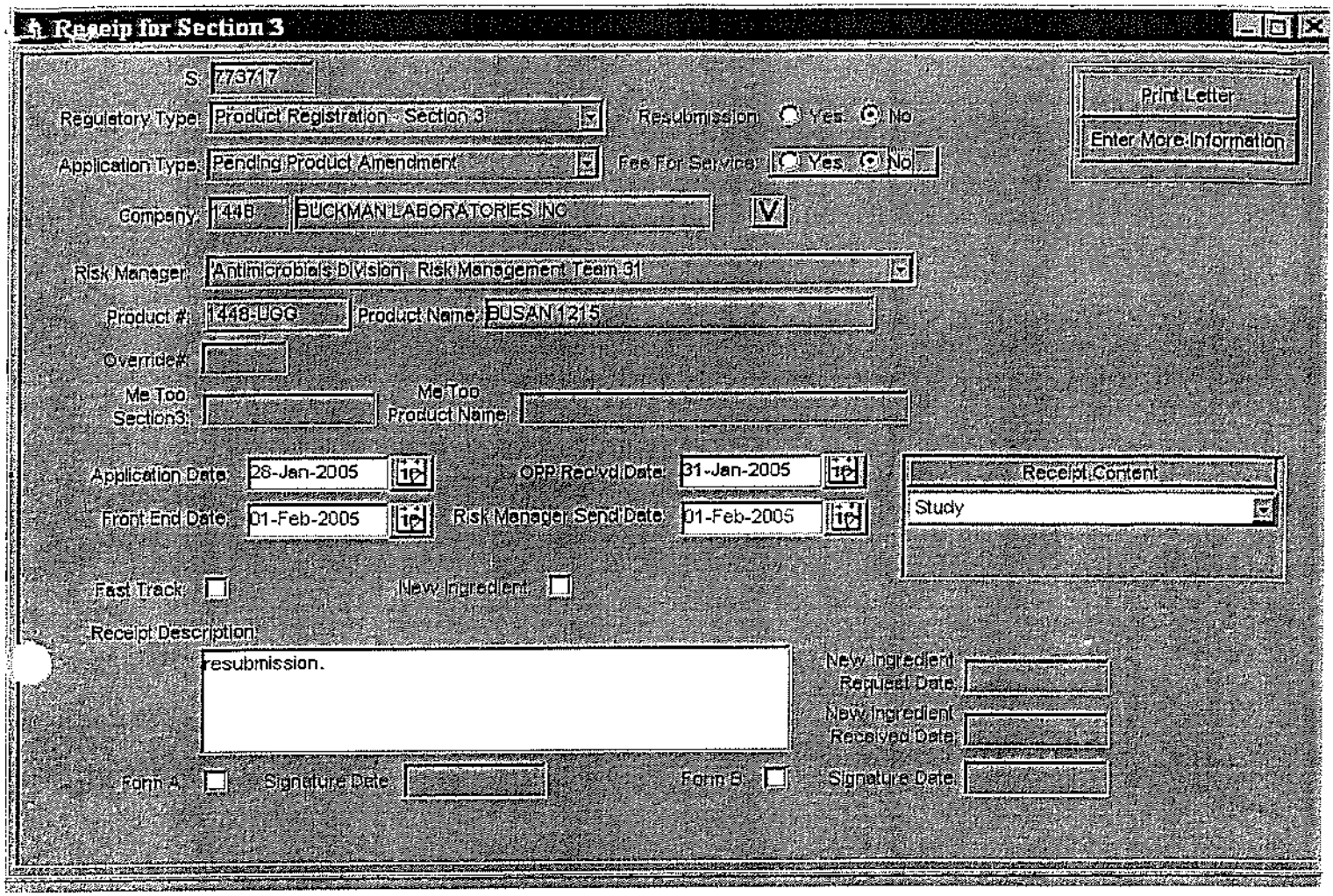
Company Official: Carl F. Watson, Ph.D.

Signature: _____

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228


Receip for Section 3
S: 773717
Regulatory Type: Product Registration - Section 3
Resubmission: Yes No
Application Type: Pending Product Amendment
Fee For Service: Yes No
Print Letter
Enter More Information
Company: 1448 BUCKMAN LABORATORIES INC
Risk Manager: Antimicrobials Division - Risk Management Team 31
Product #: 1448-UGG
Product Name: BUSAN 1215
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 28-Jan-2005
OPP Recvd Date: 31-Jan-2005
Receipt Content
Study
Front End Date: 01-Feb-2005
Risk Manager Send Date: 01-Feb-2005
Fast Track:
New Ingredient:
Receipt Description:
resubmission.
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

464581-00

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter: Buckman Laboratories, Inc.
1256 N. McLean Blvd.
Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

Resubmission of data:
BCMW, EPA File Symbol 1448-UGE
Busan 1215, EPA File Symbol 1448-UGG

3. Transmittal Date: 21 December 2004

4. List of Submitted Studies:

Vol. 1 & II: Supplemental Report: Mammalian Toxicology and Environmental Fate and Effects
Buckman Laboratories, Inc.
Report Date: January 20, 2005

Guideline Number: Waiver Requests

MRID No: 46458101

Company Official: Carl F. Watson, Ph.D.

Signature: Carl F Watson

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

4/4

464351-00

Buckman
LABORATORIES

BUCKMAN LABORATORIES INTERNATIONAL, INC.

1256 NORTH McLEAN BLVD.
MEMPHIS, TN 38108-1241 U.S.A.
TELEPHONE (901) 278-0330
FAX (901) 276-5343
www.buckman.com
e-mail: knelix@buckman.com

Via Federal Express

December 21, 2004

US Environmental Protection Agency
Document Processing Desk (New Registration)
Office of Pesticide Programs, Antimicrobial Division (PM 31)
Crystal Mall 2, Room 266A
1801 S. Bell Street
Arlington, VA 22202

Re: BCMW / BUSAN 1215 - Application for a New Pesticides

Enclosed please find an application for a new product registration for Buckman Laboratories, Inc. product: BCMW - MUP and BUSAN 1215 - EUP). Enclosed you will find the following information to support this application:

- Two (2) Applications under PRIA, one for each Pesticide Registration (MUP/EUP)
- Three (3) copies of each product Confidential Statement of Formula
- Two (2) Certifications with Respect to Citation of Data, one for each product.
- Two (2) Data Requirement Listings (Data Matrix)
- One (1) copy of Data Waiver
- Five (5) Copies of the Proposed Labeling for each product.
- Three (3) Copies of all Required Toxicology Studies

If you have any questions or require any additional information regarding this application, please feel free to contact me.

Sincerely,
BUCKMAN LABORATORIES INTERNATIONAL, INC.

Carl F. Watson, Ph.D.
Sr. Regulatory Toxicologist

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

1414 - 466

January 10, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

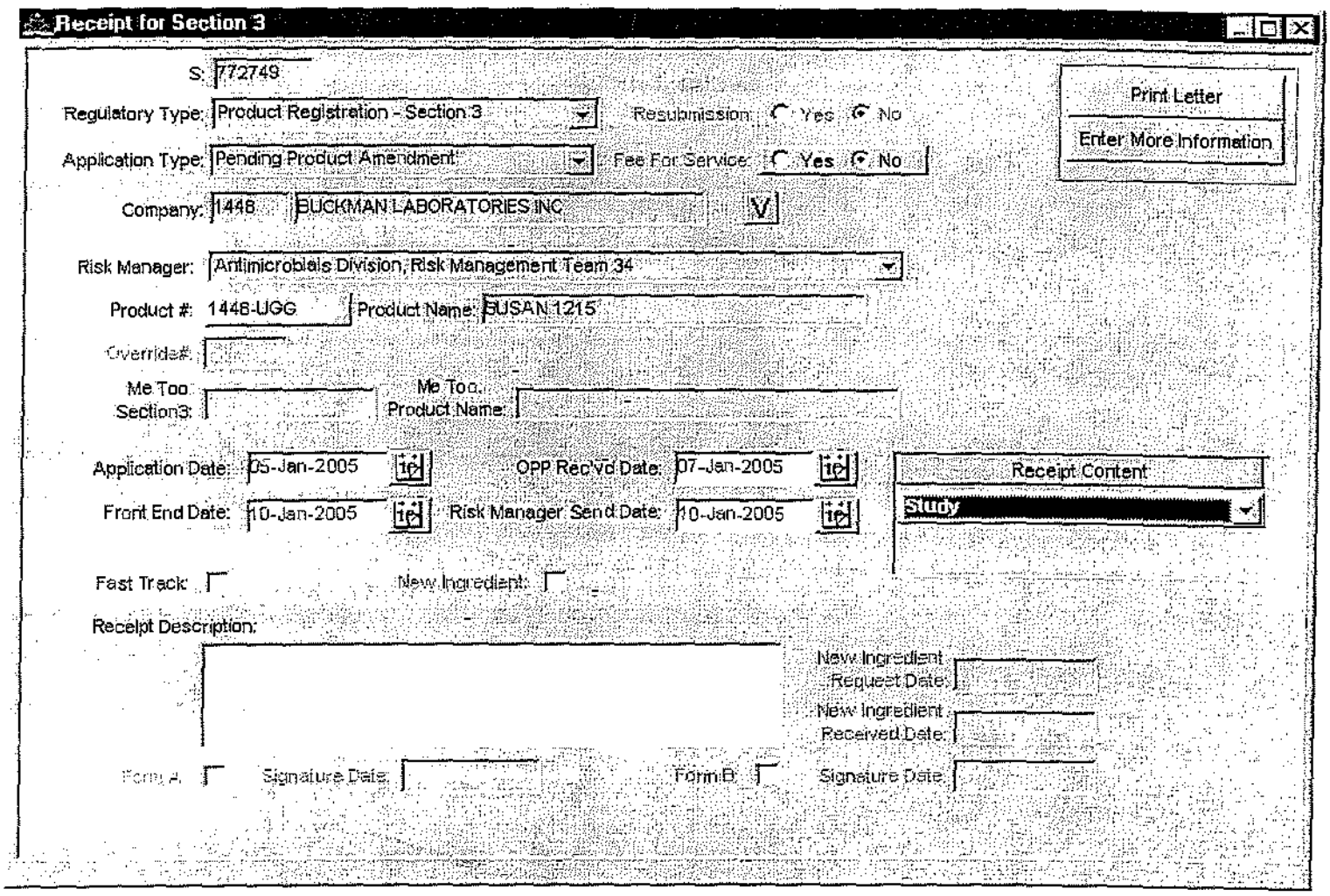
BUCKMAN LABORATORIES INC
1256 NORTH MCLEAN BLVD
MEMPHIS, TN 38108

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 07-JAN-05. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

5/6


Receipt for Section 3
S: 772749
Regulatory Type: Product Registration - Section 3
Resubmission: Yes No
Application Type: Pending Product Amendment
Fee For Service: Yes No
Print Letter
Enter More Information
Company: 1448 BUCKMAN LABORATORIES INC
Risk Manager: Antimicrobials Division, Risk Management Team 34
Product #: 1448-UGG
Product Name: BUSAN 1215
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 05-Jan-2005
OPP Rec'vd Date: 07-Jan-2005
Receipt Content
Front End Date: 10-Jan-2005
Risk Manager Send Date: 10-Jan-2005
Study
Fast Track:
New Ingredient:
Receipt Description:
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

464405-00

Buckman
LABORATORIES

BUCKMAN LABORATORIES INTERNATIONAL, INC.

1256 NORTH McLEAN BLVD.
MEMPHIS, TN 38108-1241 U.S.A.
TELEPHONE (901) 278-0330
FAX (901) 276-5343
www.buckman.com
e-mail: knetix@buckman.com

Via Federal Express

January 5, 2005

US Environmental Protection Agency
Document Processing Desk (New Registration)
Office of Pesticide Programs, Antimicrobial Division (PM 31)
Crystal Mall 2, Room 266A
1801 S. Bell Street
Arlington, VA 22202

Re: BCMW / BUSAN 1215
EPA File Symbol: 1448-UGG
Submission of New Study

Enclosed please find 3 copies of the study report below submitted in support of the new registration identified above.

Vol. 1: An Acute Oral Toxicity Study with the Northern Bobwhite
Wildlife International, Ltd
Report Date: December 22, 2004

Guideline Number: 71-1 (OPPTS 850.2100)

If you have any questions or require any additional information regarding this application, please feel free to contact me.

Sincerely,
BUCKMAN LABORATORIES INTERNATIONAL, INC.

Carl F. Watson, Ph.D.
Sr. Regulatory Toxicologist

48

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter: Buckman Laboratories, Inc.
1256 N. McLean Blvd.
Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

Data to Support New Registrations:
EPA File Symbol: 1448-UGG
BCMW – Manufacturing Use Product
Busan 1215 – End Use Product

3. Transmittal Date: 5 January 2005

4. List of Submitted Studies:

Vol. 1: An Acute Oral Toxicity Study with the Northern Bobwhite
Wildlife International, Ltd
Report Date: December 22, 2004

Guideline Number: 71-1 (OPPTS 850.2100)

MRID No: 46440501

Company Official: Carl F. Watson, Ph.D.

Signature: Carl F. Watson

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 1, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

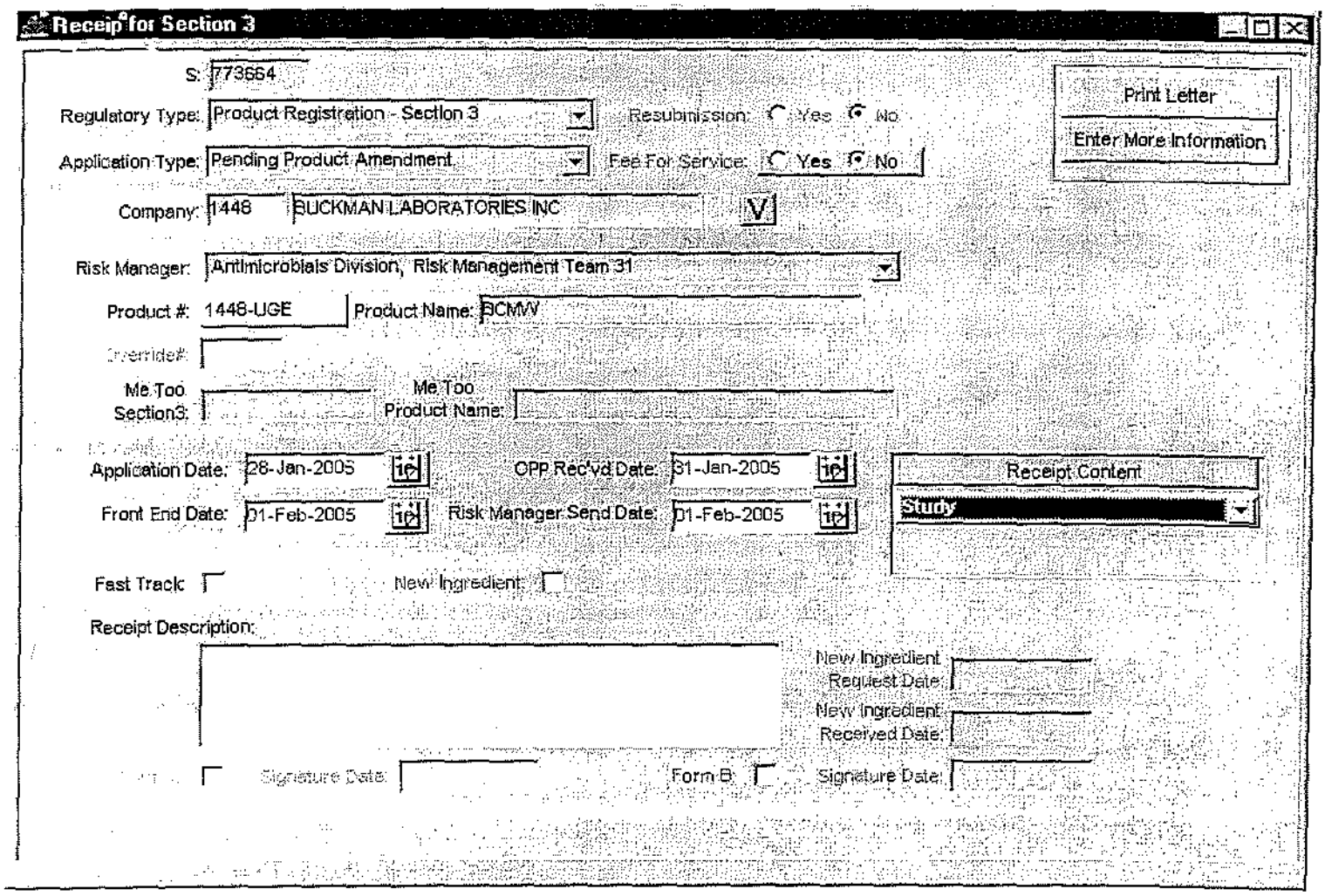
BUCKMAN LABORATORIES INC
1256 NORTH MCLEAN BLVD
MEMPHIS, TN 38108

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 31-JAN-05. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

50


Receipt for Section 3
S: 773664
Regulatory Type: Product Registration - Section 3
Resubmission: Yes No
Application Type: Pending Product Amendment
Fee For Service: Yes No
Print Letter
Enter More Information
Company: 1448 BUCKMAN LABORATORIES INC
Risk Manager: Antimicrobials Division, Risk Management Team 31
Product #: 1448-UGE
Product Name: BCMW
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 28-Jan-2005
OPP Rec'vd Date: 31-Jan-2005
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Risk Manager Send Date: 01-Feb-2005
Receipt Content
Study
Fast Track:
New Ingredient:
Receipt Description:
New Ingredient Request Date:
New Ingredient Received Date:
Signature Date:
Form B:
Signature Date:

464580-00

Buckman
LABORATORIES

BUCKMAN LABORATORIES INTERNATIONAL, INC.

1256 NORTH McLEAN BLVD.
MEMPHIS, TN 38108-1241 U.S.A.
TELEPHONE (901) 278-0330
FAX (901) 276-5343
www.buckman.com
e-mail: knetix@buckman.com

Via Federal Express

January 28, 2005

US Environmental Protection Agency
Document Processing Desk (New Registration)
Office of Pesticide Programs, Antimicrobial Division (PM 31)
Crystal Mall 2, Room 266A
1801 S. Bell Street
Arlington, VA 22202

Re: BCMW, EPA File Symbol: 1448-UGE
Submission of new data

Enclosed please find the following new study submitted in support of our application for new a registered product, BCMW (EPA File Symbol: 1448-UGE).

Vol. 1: Analytical Method Verification for the Determination of Aqueous Ammonia Solution In Freshwater.
Wildlife International, Ltd.
Report Date: 18 January 2005

If you have any questions or require any additional information regarding this application, please feel free to contact me at (901) 272-6228.

Sincerely,
BUCKMAN LABORATORIES INTERNATIONAL, INC.

Carl F. Watson, Ph.D.
Sr. Regulatory Toxicologist

52

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter: Buckman Laboratories, Inc.
1256 N. McLean Blvd.
Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

Data to Support New Registration:
BCMW – File Symbol No. 1448-UGE

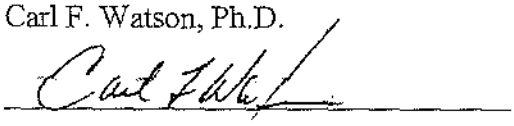
3. Transmittal Date: 28 January 2005

4. List of Submitted Studies:

Vol. 1: Analytical Method Verification for the Determination of Aqueous Ammonia Solution in Freshwater
Wildlife International, Ltd
Report Date: January 28, 2005
Study Report No. 210C-101

MRID No: 46458001

Company Official: Carl F. Watson, Ph.D.

Signature: 

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

Buckman
LABORATORIES

BUCKMAN LABORATORIES INTERNATIONAL, INC.

1256 NORTH McLEAN BLVD.
MEMPHIS, TN 38108-1241 U.S.A.
TELEPHONE (901) 278-0330
FAX (901) 276-5343
www.buckman.com
e-mail: knetix@buckman.com

Via Federal Express

July 6, 2005

US Environmental Protection Agency
Document Processing Desk (New Registration)
Office of Pesticide Programs, Antimicrobial Division (PM 31)
Crystal Mall 2, Room 266A
1801 S. Bell Street
Arlington, VA 22202

Re: BCMW / BUSAN 1215
EPA File Symbol: 1448-UGG
Submission of New Study

Enclosed please find 3 copies of the study report below submitted in support of the new registration identified above.

Vol. 1: Storage Stability and Corrosion Characteristics
Product Safety Laboratories
Report Date: June 30, 2005

Guideline Number: 63-17 / -20 (OPPTS 830.617 & 830.6320)

If you have any questions or require any additional information regarding this application, please feel free to contact me.

Sincerely,
BUCKMAN LABORATORIES INTERNATIONAL, INC.

Carl F. Watson, Ph.D.
Sr. Regulatory Toxicologist

54

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter: Buckman Laboratories, Inc.
1256 N. McLean Blvd.
Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

Data to Support New Registrations:
EPA File Symbol: 1448-UGG
BCMW – Manufacturing Use Product
Busan 1215 – End Use Product

3. Transmittal Date: 6 July 2005

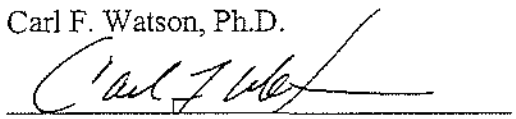
4. List of Submitted Studies:

Vol. 1: BUSAN 1215: Storage Stability and Corrosion Characteristics
Product Safety Laboratories
Report Date: June 30, 2005

Guideline Numbers: 63-17/20 (OPPTS 830.617 & 830.6320)

MRID No: 46588801

Company Official: Carl F. Watson, Ph.D.

Signature: 

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: December 20, 2004	EPA Reg No./File Symbol: 1448-	Page 1 of 5
Applicant's/Registrant's Name & Address: Buckman Laboratories, Inc. 1256 North McLean Blvd. Memphis, TN 38108	Product BCMW	
Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550 (61-1)	Product Identity / Disclosure of Ingredients	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.1600 (61-2a)	Beginning Materials	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.1650 (61-2a)	Description of Formulation Process	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830-1670 (61-2b)	Discussion of Formation of Impurities	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.1700 (62-1)	Preliminary Analysis	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.1750 (62-2)	Certified Limits	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.1800 (62-3)	Enforcement Analytical Method	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.6302 (63-02)	Color	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.6303 (63-03)	Physical State	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.6304 (63-04)	Odor	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.6313 (63-13)	Stability	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.6314 (63-14)	Oxidation / Reduction	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.6315 (63-15)	Flammability	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.6316 (63-16)	Explodability	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.6317 (63-17)	Storage Stability	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review

Signature	Name and Title	Date
Carl F Watson	Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	12/20/04

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: December 20, 2004	EPA Reg No./File Symbol: 1448	Page 2 of 5
Applicant's/Registrant's Name & Address: Buckman Laboratories, Inc. 1256 North McLean Blvd. Memphis, TN 38108	Product **BCMW**	

Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319 (63-19)	Miscibility	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830-6320 (63-20)	Corrosion characteristics	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.6321 (63-21)	Dielectric breakdown voltage	N/A		Not Applicable	
830.7000 (63-12)	pH	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.7100 (63-18)	Viscosity	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.7200 (63-5)	Melting point	N/A		Not Applicable	
830.7220 (63-6)	Boiling point	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.7300 (63-7)	Density / relative density / bulk density	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.7370 (63-10)	Dissociation constant in water	N/A	Buckman Laboratories, Inc.	PL	Registration App. in review
830.7570 (63-11)	Octanol / water partition coefficient	N/A		Not Applicable	
830.7860 (63-8)	Water solubility	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
830.7950 (63-9)	Vapor pressure	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review

Signature Carl F Watson	Name and Title Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	Date 12/20/04

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 20, 2004	EPA Reg No./File Symbol 1448-	Page 3 of 5
Applicant's/Registrant's Name & Address: Buckman Laboratories International, Inc. 1256 North McLean Blvd. Memphis, TN 38108	Product **BCMW**	
Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
ECOLOGICAL EFFECTS					
850.1010 (72-2a)	Invertebrate Toxicity	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
850.1075 (72-1a)	Fish Toxicity Bluegill sunfish	N/A	Buckman Laboratories, Inc.	OWN	Regisfration App. in review
850.1075 (72-1c)	Fish Toxicity Rainbow Trout	N/A	Buckman Laboratories, Inc.	OWN	Registrafion App. in revlew
850.1400 (72-4)	Fish Early-Life Stage Toxicity	N/A	Buckman Laboratories, Inc.	Waiver/PL	Registration App. in review
850.1500 (72-5)	Fish Life-cycle Toxicity	N/A	Buckman Laboratories, Inc.	Waiver/PL	Registration App. In review
850.2100 (71-1)	Acute Avian Oral – Quail/Duck	N/A	Buckman Laboratories, Inc.	OWN	Registration App. In review

Signature	Name and Title	Date
Carl F Watson	Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	12/20/04

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: December 20, 2004	EPA Reg No./File Symbol: 1448-	Page 4 of 5
Applicant's/Registrant's Name & Address: Buckman Laboratories, Inc. 1256 North McLean Blvd. Memphis, TN 38108	Product BCMW	

Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
TOXICOLOGY					
870.1100 (81-1)	Acute Oral Toxicity	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
870.1200 (81-2)	Acute Dermal Toxicity	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
870.1300 (81-3)	Acute Inhalation Toxicity	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
870.2400 (81-4)	Acute Eye Irritation	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
870.2500 (81-5)	Acute Dermal Irritation	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
870.2600 (81-6)	Skin Sensitization	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
870.3250 (82-3)	90-Day Dermal - Rodent	N/A	Buckman Laboratories, Inc.	Waiver/PL	Registration App. in review
870.3700 (83-3)	Developmental Toxicity	N/A	Buckman Laboratories, Inc.	Waiver/PL	Registration App. in review
870.5100 (84-2)	Gene Mutation (Ames Test)	N/A	Buckman Laboratories, Inc.	Waiver/PL	Registration App. in review
870.5300 (84-2)	Structural Chromosomal	N/A	Buckman Laboratories, Inc.	Waiver/PL	Registration App. in review
870.5550 (84-2)	Other Genotoxic Effects	N/A	Buckman Laboratories, Inc.	Waiver/PL	Registration App. in review
870.6200 (81-8)	Acute Neurotoxicity	N/A	Buckman Laboratories, Inc.	Waiver/PL	Registration App. in review
870.7800 (85-7)	Immunotoxicity	N/A	Buckman Laboratories, Inc.	Waiver/PL	Registration App. in review

Signature	Name and Title	Date
Carl F. Watson	Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	12/20/04

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: December 20, 2004	EPA Reg No./File Symbol 1448-	Page 5 of 5
Applicant's/Registrant's Name & Address: Buckman Laboratories International, Inc. 1256 North McLean Blvd. Memphis, TN 38108	Product BCMW	

Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 875.1000	Product Use Information	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
OPPTS 875.1200	Dermal Exposure Indoor	N/A	Buckman Laboratories, Inc.	Waiver	Registration App. in review
OPPTS 875.1400	Inhalation Exposure Indoor	N/A	Buckman Laboratories, Inc.	Waiver	Registration App. in review
OPPTS 875.2800	Description of Human Activity	N/A	Buckman Laboratories, Inc.	OWN	Registration App. in review
ENVIRONMENTAL FATE, TRANSPORT					
OPPTS 835.2110 (161-1)	Hydrolysis	N/A	Buckman Laboratories, Inc.	Waiver	Registration App. in review

Signature	Name and Title	Date
Carl F. Watson	Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	12/20/04

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: December 20, 2004	EPA Reg No./File Symbol 1448-	Page 1 of 5
Applicant's/Registrant's Name & Address: Buckman Laboratories, Inc. 1256 North McLean Blvd. Memphis, TN 38108	Product BCMW	

Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
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			Buckman Laboratories, Inc.	OWN	Registration App. in review

Signature	Name and Title	Date
Carl F. Watson	Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	12/20/04

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: December 20, 2004	EPA Reg No./File Symbol 1448 - [redacted]	Page 2 of 5
Applicant's/Registrant's Name & Address: Buckman Laboratories, Inc. 1256 North McLean Blvd. Memphis, TN 38108	Product BCMW	

Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
				Not Applicable	
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
				Not Applicable	
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	PL	Registration App. in review
				Not Applicable	
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review

Signature Carl F Watson	Name and Title Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	Date 12/20/04

Form Approved OMB No. 2070-0060

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401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: December 20, 2004	EPA Reg No./File Symbol 1448- [redacted]	Page 3 of 5
Applicant's/Registrant's Name & Address: Buckman Laboratories International, Inc. 1256 North McLean Blvd. Memphis, TN 38108	Product **BCMW**	

Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	Waiver/ PL	Registration App. in review
			Buckman Laboratories, Inc.	Waiver/ PL	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review

Signature	Name and Title	Date
Carl F Watson	Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	12/20/04

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: December 20, 2004	EPA Reg No./File Symbol 1448- [redacted]	Page 4 of 5
Applicant's/Registrant's Name & Address: Buckman Laboratories, Inc. 1256 North McLean Blvd. Memphis, TN 38106	Product BCMW	

Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
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			Buckman Laboratories, Inc.	Waiver/PL	Registration App. in review

Signature	Name and Title	Date
Carl F. Watson	Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	12/20/04

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

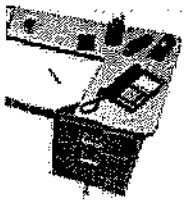
Date: December 20, 2004	EPA Reg No./File Symbol 1448- [redacted]	Page 5 of 5
Applicant's/Registrant's Name & Address: Buckman Laboratories International, Inc. 1256 North McLean Blvd. Memphis, TN 38108	Product BCMW	

Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]				OWN	Registration App. in review
				Waiver	Registration App. in review
				Waiver	Registration App. in review
				OWN	Registration App. in review
				Waiver	Registration App. in review

Signature	Name and Title	Date
Carl F. Watson	Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	12/20/04

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 352404	**Registration#: 1448-UGG**	
Fee Category: A46	**PRIA Decision Time Frame: 10 months**	
Submitted by: Drusilla Copeland/Velma Noble	**Branch: RMBI**	**Date: 8/23/06**
Company: Buckman Laboratories International, Inc.		
Original Due Date: 4/08/06	**Proposed New Due Date: 6/08/07**	
Previous Negotiated Due Dates: 9/8/06		
Issue (describe in detail): The Agency required Buckman to contact FDA regarding a tolerance for Cloramine. FDA has told Buckman they need to file a Food Contact Notification (FCN). The Company requires a time extension in order to prepare this FCN and obtain an FDA review of it. The agency cannot approve this application in the absence of a FCN.		
Describe Interactions with Company: The Agency called the consultant on 8/22/06 concerning the FDA approval. The Company replied with faxed letter on 8/22/06 which request 10 months extension in order to go through the FDA Food Contact Notification process.		
Rationale for Proposed Due Date: The additional 10 months should allow time for the data to be reviewed by FDA.		
Other Comments:		
Approved: ✓	**Disapproved:**	
If disapproved, action to be taken:		
OD or DOD Signature: [signature] 8-31-06		



Drusilla Copeland/DC/USEPA/US
08/23/2006 09:07 AM

To Michael Hardy/DC/USEPA/US@EPA
cc Dennis Edwards/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA
bcc
Subject Renegotiated for 1448-UGE and 1448-UGG

Good morning all, Here is the negotiated form and email from Buckman

 1448-UGE negeotiation letter new.doc

 1448-UGG negeotiation letter new.doc

RE: EPA File Symbols 1448-UGE & 1448-UGG

Drusilla,

Buckman Laboratories would like to re-negotiate an extension on the current PRIA due date of September 8, 2006 for the two referenced pending registration applications. We do not believe that the FDA matter can be realistically resolved in a timeframe to meet the current PRIA deadline and request a minimum of a 10 month extension, making the new deadline sometime in June, 2007.

In response to EPA's request that Buckman obtain FDA's opinion regarding a 409 tolerance for chloramine, Buckman submitted information to FDA regarding this matter. In FDA's response back to Buckman, the Agency stated that they could not render an opinion without assessing the available chloramine data, recommending that an FCN (Food Contact Notification) be filed. Buckman has subsequently discussed this issue with several consultants as to how best to proceed. Our company has in-listed the services of a consulting firm and will be requesting a Pre-Notification meeting with FDA which will take several weeks to set. Following this meeting it is our expectation that an FCN will be prepared and submitted to FDA for consideration. It's my understanding that a formal FCN review takes 120 days once the submission is deemed 'complete'. Once FDA makes it's determination, your Agency will require some time for consideration and issuance of the registrations.

The apparent time frames involved for these procedural steps will easily exceed the current PRIA deadline for our registration; thus, the need for our request. Please be assured that it's our desire to work out this matter in a timely manner as possible.

Buckman appreciates your consideration of this matter.

Regards,
Carl Watson, Ph.D.
Sr. Regulatory Toxicologist
Buckman Laboratories International, Inc.
(901) 272-6228

MAR 1 2006

Mr. Carl F. Watson, Ph. D.
Sr. Regulatory Toxicologist
Buckman Laboratories, Inc.
1256 N. McLean Blv.
Memphis, TN 38108

Dear Mr. Watson:

Subject: **EPA File Symbol Numbers 1448-UGG Busan 1215**
Application Dated: December 21, 2004
EPA Receipt Date: December 23, 2004

The Agency has conducted a partial review of the data submitted in support of file symbol numbers 1448-UGG. We will notify you when additional reviews are completed.

Proposed Request:

- Application for new product registration

Review of Ecological Effects Studies Data Reviews:

1. *Acute Oral Toxicity Review for 1448-UGG Busan 1215:*

Acute Oral Toxicity Study with Northern Bobwhite:

The acute oral toxicity study is acceptable for a formulated product test; however, no explanation was included as to why a TGAI (using >80% a.i.) Acute oral test was not conducted. The TGAI test is still required for registration of Busan 1215, unless adequate justification for performing the test only with formulated product is submitted.

Residue for the Manufacture of Paper and Paperboard Products:

2. Paper making process is an indoor use and hydrolysis study is a data requirement No hydrolysis study is submitted. A literature reference states that chloramine hydrolyzes slowly in aqueous solution. Although no hydrolysis study is required at this time, one may be needed for additional uses or when this chemical is reassessed.

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CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

3. Chloramine does not appear to have a clearance from the FDA for use as a slimicide. Although Chloramine is not an ingredient in the formulation, it is present as a result of a chemical reaction between the product when it is used in conjunction with sodium hypochlorite (12.5%) to form monochloramine.

Before we can grant registration for this product, you must contact FDA regarding the potential presence of chloramine in paper that may contact food. You must provide a letter from FDA regarding the need or lack of need for a 409 tolerance for chloramine.

The PRIA due date for this application is April 8, 2006. If the situation with FDA cannot be resolved before March 8, 2006 you need to re-negotiate the PRIA due date by proposing a new date. You can do this via letter or e-mail.

Before proposing a new PRIA date, you also need to respond back with an explanation/justification for performing an acute oral toxicity study only with the formulated product and not the TGAI. A TGAI study is required.

In summary, a letter form FDA on chloramine is needed as well as a justification on the Avian oral toxicity study described above. Any PRIA re-negotiation should also factor in our review time.

Other Comments:

For detailed information and considerations, please refer to the enclosed EPA/AD Review of Ecological Effects Studies and Hazard Assessment for Ammonia and Monochloramine in the Manufacture of paper and paperboard products.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosures: Reviews Dated December 9, 2005, October 25, 2005 and January 9, 2006

Buckman
LABORATORIES

BUCKMAN LABORATORIES INTERNATIONAL, INC.

1256 NORTH McLEAN BLVD.
MEMPHIS, TN 38108-1241 U.S.A.
TELEPHONE (901) 278-0330
FAX (901) 276-5343
www.buckman.com
e-mail: knetix@buckman.com

Via Federal Express

February 15, 2006

Ms. Velma Noble, PM 31
US EPA, OPP, AD, RMB I (7510C)
Crystal Mall 2, Room 266A
1801 S. Bell Street
Arlington, VA 22202

Re: BCMW, EPA File Symbol 1448-UGE
BUSAN 1215, EPA File Symbol 1448-UGG
Response to Agency's Data Review Comments

Buckman appreciates the faxed review comments concerning our pending registrations, EPA File Symbols: 1448-UGE & UGG. In looking through the comments, it appears that there were several issues raised by the scientists that need addressing. These issues are listed below along with Buckman's responses:

1) Acute Avian Tox on the TGAI - This requirement should be filled once it's clear to the scientist that the MUP (BCMW, File Symbol 1448-UGE) & EUP (Busan 1215, File Symbol 1448-UGG) ('mother-and-child') are one-in-the-same. The data residing at EPA should be applicable to both products.

2) Hydrolysis study on monochloramine – this request concerns us in regard to delaying the issuance of our registration for the follow of reasons:

- As explained in our preliminary meeting with EPA in September, 2004, Buckman Laboratories presented its intent to register 1448-UGG/UGE as a slimicide for the manufacture of pulp and paper. The active ingredient being registered is ammonia. The environmental fate of ammonia is well understood and discussed in the information submitted in our application.
- A hydrolysis study should not be necessary as neutralization of any chloramine residuals by addition of sodium metabisulfide is specified on the EUP label. The neutralization step mitigates chloramine residuals from reaching the environment; therefore, should eliminate the need for a hydrolysis study.

3) FDA allowance of Chloramine - Buckman will contact FDA to discuss this issue. Because this matter may impact the PRIA timeframe for our application, once we've talked with FDA Buckman will follow-up with EPA to determine the best alternatives to address this matter relative to the pending registration decision.

If you have any questions or require any additional information regarding this application, please feel free to contact me.

Sincerely,
BUCKMAN LABORATORIES INTERNATIONAL, INC.

Carl F. Watson, Ph.D.
Sr. Regulatory Toxicologist

Kathryn Montague/DC/USEPA/US
02/21/2006 03:27 PM

To: Dennis Edwards/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA
cc:
bcc:
Subject: Busan 1215 question

Hi, Dennis and Velma,

I looked back at the memo I did to go with the DERs in October....it looks like they were all conducted with the 7.6% product. The reason I had an issue with the avian oral is that there was no justification for testing such a low % product as the TGAI, especially since they didn't get any mortality at the levels tested (2250 mg product/kg, which is only 171 mg ai/kg)...we need to have an LD50 >2250 mg ai/kg to call the chemical practically non-toxic. The formulated product would be practically non-toxic in this case, but all we can say about the TGAI is that is is at least at most moderately toxic to birds. The fish and daphnid studies tested high enough to get over the 100 mg ai/L range, so we have a lot more confidence in our toxicity classification for the chemical.

Hope this helps...

Kay

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

January 30, 2006

MEMORANDUM

SUBJECT: Occupational Exposure Considerations for Proposed Industrial End-Use Product ***BUSAN 1215***: New Use Pattern for the Active Ingredient **Ammonia** in Pulp and Paper Mill Process Water Systems.

TO: Dennis Edwards, Chief
Velma Noble, Product Manager, Team 31
Regulatory Management Branch I
Antimicrobials Division (7510C)

FROM: Doreen Aviado, Biologist Doreen Aviado 1/30/06
Team Two
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

THRU: Kathryn Montague, Acting Team Leader Kathryn V. Montague 2/1/06
Team Two
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Norm Cook, Chief 2/8/06
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

DP Barcode: D313640

Pesticide Chemical/No.: Ammonia / 005302

Registrant: Buckman Laboratories, Inc.

EPA File Symbol(s): 1448-UGE: *BCMW* (MUP for Formulator Use)
1448-UGG: *BUSAN 1215* (Industrial End-Use Product – *repack of BCMW*)

MRID No.: 464581-01

Action Requested:

The Antimicrobials Division (AD), Product Management Team 31, requested that the Risk Assessment and Science Support Branch (RASSB) conduct an occupational exposure assessment in support of the proposed industrial end-use product *BUSAN 1215* (EPA File Symbol 1448-UGG) containing 7.59% ammonia (total) as the active ingredient. Ammonia is currently registered as an active ingredient at 0.2% in only one product, AANKILL 44 (EPA Reg. No. 63709-1), an insecticide against fire ants. Therefore, the proposed industrial use of *BUSAN 1215* to control algal, bacterial and fungal deposits in pulp/paper mill process water systems constitutes a "new use" for the active ingredient.

An exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For *BUSAN 1215,* toxicological hazard has been identified for ammonia concentrates as acute dermal corrosivity and irritation to the respiratory system. Protecting occupational workers against dermal/eye injury and respiratory tract/mucosal damage from off-gassing of ammonia vapor (due to its high vapor pressure) is of particular concern for workplace safety. However, the exposure criterion is not met since proposed use conditions [closed-system delivery, personal protective equipment (PPE), industrial safety guidelines for monitoring of airborne ammonia] will negate any contact with ammonia in the workplace. Therefore, only a "qualitative" assessment is presented to address potential occupational (handler and postapplication) exposures from use of *BUSAN 1215* in industrial pulp and paper mill process water systems used in manufacturing food-contact pulp/paper and paperboard.

Review Outcome:

Based upon review of the submitted data for proposed registration of *BUSAN 1215* microbicide, AD/RASSB anticipates that the product will pose limited dermal/inhalation exposure concern for paper mill workers when handled and applied under conditions of use stipulated on the draft labeling and in Buckman's report (MRID 464581-01) detailing intended product use methods/worker activities, including exposure mitigation measures such as PPE and engineering controls, and industrial workplace monitoring of airborne ammonia.

The *BUSAN 1215* product formulation contains a low percentage of ammonia as a dilute aqueous solution (acute product toxicity category IV). The registrant stipulates handling of product by trained Buckman representatives only and mandatory use of dermal PPE. *(Note: PPE language should be added to product labeling precautionary statements.)* It is transported in sealed tote bins which are then attached to a closed, metering system. The product is pumped into the paper mill water system via a fixed piping and feed system (i.e., chemical feed skid). The mixing proportions for dosing the system are designed to consume a significant portion of the available ammonia. Overall, the product use conditions minimize any potential acute and chronic exposure risks for occupational handler/postapplication tasks.

As it pertains to worker exposure, this AD/RASSB review supports allowing the "new use" pattern for ammonia and identifies no obstacles for *BCMW/BUSAN 1215* product registration. We concur with Buckman's statements that: *"The low potential acute systemic toxicity, the restriction of the product to industrial use, protective closed-system application*

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equipment and established regulatory guidelines for ammonia assure that this product can be safely used when handled according to label instructions."

Any future changes to the product use pattern and/or conditions of use will prompt AD/RASSB to reassess human exposure potential for *BUSAN 1215*.

Background:

The registrant held preliminary discussions with AD/RASSB in August and September of 2004 in preparation for submission of an acceptable registration application in January, 2005 for both a proposed manufacturing-use product (MUP) and industrial end-use product (EP) as *BCMW* and *BUSAN 1215* respectively. The EP, *BUSAN 1215* (EPA File Symbol 1448-UGG) is a direct repack of the formulator-use MUP, *BCMW* (EPA File Symbol 1448-UGE). Both products contain 7.59% aqueous ammonia (total ammonia) as a dilute ammonium solution formed from [redacted] *BUSAN 1215* is applied in conjunction with a sodium hypochlorite source (12.5% a.i.) to form "monochloramine" in-situ, as the active component (microbicide) for treating pulp/paper mill water systems.[2, 3]

BUSAN 1215 was initially proposed for use in a variety of industrial cooling water system applications (e.g., cooling towers, recirculating cooling water systems, brewery/food pasteurizers, evaporative condensers, decorative fountains, and sewage/ wastewater systems) which have since been dropped from consideration by the registrant. Only the pulp/paper mill water system use patterns remain for exposure assessment. AD/RASSB will address separately (under DP Barcodes D313638 and D313639) any dietary concerns for potential ingestion of monochloramine residues leached from manufactured food-contact paper/paperboard.

To facilitate review, Buckman Laboratories, Inc. submitted draft labeling for *BCMW/ BUSAN 1215*, and data on product use (Series 875 GLN 875.1700 and 875.2700) and description of human activities (Series 875 GLN 875.2800) were provided in the Supplemental Report *"Mammalian Toxicology and Environmental Fate and Effects Data"* (MRID 464581-01) received January 31, 2005.

Overview of Product Use:

The registrant-submitted documents indicate the following product use profile for the proposed *BUSAN 1215* industrial end-use product.

[redacted]

[2] Numerous sodium hypochlorite (12% a.i.) source products (e.g., *BUSAN 1125C*, EPA Reg. No. 1448-20001) are currently registered with the Agency for use as microbicides in treating industrial process water systems (including paper mills). Therefore, the use of sodium hypochlorite for water system chlorination is an established use pattern, not subject to reassessment in support of the proposed registration of *BUSAN 1215*.

[3] The monochloramine generation process is consistent with certain alternate disinfection techniques used for public drinking water systems where ammonia and hypochlorite react in water for "chloramination".

Table 1. *BUSAN 1215* Use Profile

Pulp and Paper Mill Process Water Systems (Microbicide)	***BUSAN 1215:*** This product is used for the control of algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products. [a]
Formulatiou	Liquid Conceutrate (Supplied in semi-bulk shipment of sealed "transfer" tote bins.)
Active Ingredient % (PC Code)	*Ammonia (total)* (7.59%) *(aqueous ammonia)* (005302) (A dilute ammonium solution formed from [redacted]
Product Density	Bulk Density 9.59 lbs/gallon
Vapor Pressure	*Volatile* as 7510 mm Hg at 25 °C for aqueous ammonia.
Personal Protective Equipment (PPE)	***Per Labeling:*** Signal Word: CAUTION. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. ***Per Product Use Data:*** Trained Buckman representatives wear Dermal PPE for all handler tasks: protective eye-wear (goggles, face shield or safety glasses), impervious chemical-resistant gloves, and full body clothing (long sleeved shirt and long pants; socks and shoes) when handling. Inhalation PPE not specified since inhalation potential negated with use of engineering controls for closed metered delivery and established regulatory airborne exposure limit guidelines for ammonia. Although inhalation exposure is not anticipated due to use of engineered delivery systems (closed, metered feed) exposure values have been established for Ammonia which allow protective airborne monitoring for industrial workplace safety. Exposure Values a. IDLH: 300 ppm (NIOSH, 1997) b. TLV (8-hour TWA): 25 ppm (ACGIH, 1999) c. TLV STEL (15-minute TWA): 35 ppm (ACGIH, 1999) d. NIOSH REL (10-hour TWA): 25 ppm (18 mg/m3) e. NIOSH STEL (15-minute TWA): 35 ppm (27 mg/m3) f. OSHA PEL (8-hour TWA): 50 ppm (35 mg/m3) Legend : IDLH = Immediately dangerous to life and health ; NIOSH = National Institute of Occupational Safety and Health; TLV = Threshold limit value; TWA = Time-weighted average; STEL = Short-term exposure limit; ACGIH = American Conference of Governmental Industrial Hygienists; REL = Recommended exposure limit; OSHA = Occupational Safety and Health Administration; and PEL = Permissible exposure limit.

Use Application and Dosage Rates	*Per Labeling: Use Application* **Pulp and Paper Mills:** This product is applied in conjunction with sodium hypochlorite (12.5%) to form monochloramine, a slower acting less aggressive oxidizing microbicide. The products are added to dilution water to achieve a minimum molar ratio of 1.5:1 of ammonia to oxidant, and this ratio is obtained by combining 0.6 fluid ounces of *BUSAN 1215* to 1 fluid ounce of sodium hypochlorite (12.5%). To ensure both handling safety and effectiveness, the monochloramine solution should be generated and fed into the treatment water systems through a proper chemical feed skid only by a trained Buckman representative. Use of this product for any other purposes or contrary to the use directions specified below is prohibited. Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained. The frequency of feeding and the duration of the treatment will depend on the severity of the problem.
Mix/Load/Application Method	*Per Product Use Data:* **Application system (closed, metered equipment)** The product will be handled and applied only by trained Buckman representatives via engineering controls (Buckman semi-bulk transfer and chemical handling systems). Mixer/Loader: *BUSAN 1215* is packaged as semi-bulk "transfer" tote bins which connect directly to a base tote feed container via specialized fittings (discharge valve/discharge hose). A small vent cap located on top of the transfer tote is opened to prevent vapor lock allowing for closed gravity flow transfer (loading). Operators are not exposed directly to any material via inhalation during unloading due to the location of the small vent cap and where they are standing when they open the transfer valves (vent cap is above them). The loading process takes less than 10 minutes. All personnel are required to use proper **PPE** when handling. Application: After loading, the tote containing the chemical hooks directly to a feed skid with the use of Kam-Lok quick fit connectors and open/close valves. Further safety measures taken to keep personnel exposure to a minimum is the addition of a containment vessel so that if a leak should occur, or some circumstance requires the totes to be moved, the small quantity of chemical left in the connection hose can be drained to the containment vessel for disposal. Use of dedicated skid-mounted chemical dosing system ensures closed delivery of both aqueous ammonia (*Busan 1215*) and sodium hypochlorite (12 % a.i.) into water systems for closed in-situ generation of monochloramine solution. Feeding of the reactant product (monochloramine) is through a double-lined, hard-pipe into the application site. (See rough schematic in Appendix A.)

Source: Registrant submitted *BUSAN 1215* draft labeling of December 21, 2004 and related product use data (MRID 464581-01) received January 31, 2005.

[a] *BUSAN 1215* is proposed for use in maintaining the integrity of paper mill process water systems. In contrast to paper mill "preservative use patterns", *BUSAN 1215* is not intended to preserve papermaking substrates, such as: pulp/broke, paper coatings, slurries, emulsions or papermaking chemicals/inks.

Toxicological Considerations:

An overview of toxicological considerations are presented below based on a toxicology review memorandum, *"Hazard Assessment for Ammonia and Monochloroamine"* by Deborah Smegal, MPH, Toxicologist (DP Barcode D313637) dated December 9, 2005. Refer to this review for complete details on hazard characterization and data citations. Certain text are excerpted below.

The primary toxicity hazard identified for ammonia concentrates is acute dermal corrosivity and irritation to the respiratory system. Protecting occupational workers against dermal/eye injury and respiratory tract/mucosal damage from off-gassing of ammonia vapor (due to its high vapor pressure) is of particular concern for workplace safety.

There is no evidence that ammonia is a carcinogen. Nor does it appear to be mutagenic. Data are unavailable for assessing developmental/reproductive effects. Studies in the scientific literature indicate potential neurological effects in humans following inhalation/dermal exposure.

Acute Toxicity of Ammonia (Technical Source Chemicals and Industrial Concentrates)

Ammonia is a corrosive substance and the main toxic effects are restricted to the sites of direct contact (i.e., skin, eyes, respiratory tract, mouth, and digestive tract). It is an upper respiratory irritant in humans. The skin is extremely sensitive to both airborne ammonia and ammonia dissolved in water. Dermal exposures to liquid ammonia or concentrated solutions and/or ammonia gas are frequently occupationally related and produce cutaneous burns, blisters, and lesions of varying degrees of severity. The topical damage caused by ammonia is probably due mainly to its reactivity and irritation properties. Its high water solubility allows it to dissolve in moisture on these surfaces, react with fatty substances, be absorbed into deeper layers, and inflict extensive damage. The severity of the damage is proportional to the concentration and duration of exposure; flushing with water immediately after contact alleviates or prevents effects (ATSDR 2004). [Source: Agency for Toxic Substances and Disease Registry (ATSDR). September 2004. Toxicological Profile for Ammonia. U.S. Dept. of Health and Human Services:]

Acute Toxicity of BUSAN 1215

In aqueous solution, ammonia exists in equilibrium with ammonium hydroxide. Ammonia solutions can cause severe eye/dermal damage due to their caustic nature. However, as noted above, the effects are dependent on the concentration of ammonia in the solution and the duration of exposure. The proposed *BUSAN 1215* product contains a dilute ammonium concentration. Based on a review of registrant-submitted data for *BCMW/BUSAN 1215*, the following low acute toxicity potential (Toxicity Category IV) was shown for the product formulation:

Table 2. Acute Product Toxicity Data on Busan 1215			
Guideline No./ Study Type	MRID No.	Results	Toxicity Category
870.1100 Acute oral toxicity	464351-08	LD_{50} > 5000 mg/kg	IV
870.1200 Acute dermal toxicity	464351-09	LD_{50} > 5000 mg/kg	IV
870.1300 Acute inhalation toxicity	464351-10	LC50 ≥ 2.08 mg/L (4-hr)	IV
870.2400 Acute eye irritation	464351-11	Minimally irritating (rabbit) Irritation cleared within 48 hours	IV
870.2500 Acute dermal irritation	464351-12	Slightly irritating	IV
870.2600 Skin sensitization	464351-13	Not a skin sensitizer (guinea pig)	NA

Source: March 16, 2005 Review Memoranda, I. Blackwell, Biologist, AD/PSB, DP Barcodes D313223 and D313227.

Inhalation Toxicity Endpoint Selection

Epidemiological Study Selected: Holness, D.L. et al. (1989) *Acute and chronic respiratory effects of occupational exposure to ammonia.* Am. Ind. Hyg. Assoc. J. 50(12):646-650.

Executive Summary: Holness et al. (1989) investigated production workers exposed to ammonia in a soda ash facility. All of the available 64 production workers were invited to participate and 82% agreed to be evaluated. The control group consisted of 31 other plant workers from stores and office areas of the plant without previous exposure to ammonia. The mean age of the workers was 38.9 years and duration of exposure was 12.2 years. Weight was the only statistically significant difference in demographics found after comparing height, weight, years worked, % smokers and pack-years smoked. The mean TWA ammonia exposures based on personal sampling over one work shift (average sample collection 8.4 hours) of the exposed and control groups were 9.2 ppm (6.4 mg/cu.m) and 0.3 ppm (0.21 mg/cu.m), respectively.

A questionnaire was administered to obtain information on exposure and work histories and to determine eye, skin and respiratory symptomatology (based on the American Thoracic Society [ATS] questionnaire [Ferris, 1978]). Spirometry (FVC, FEV-1, FEF50 and FEF75) was performed according to ATS criteria at the beginning and end of each work shift on the first workday of the week (day 1) and the last workday of the week (day 2). Differences in reported symptoms and lung function between groups were evaluated using the actual values and with age, height and pack-years smoked as covariates in linear regression analysis. Baseline lung function results were expressed as percent of predicted values calculated from Crapo et al. (1981) for FVC and FEV-1 and from Lapp and Hyatt (1967) for FEF50 and FEF75.

No statistical difference in the prevalence of the reporting of symptoms was evident between the exposed and control groups, although workers reported that exposure at the plant had aggravated specific symptoms including coughing, wheezing, nasal complaints, eye irritation, throat discomfort and skin problems. Based on the lack of subjective symptomatology and changes in spirometry, this study establishes a free-standing TWA NOAEL of 9.2 ppm (6.4

mg/cu.m). Adjustment for the TWA occupational scenario results in a NOAEL(HEC) of 2.3 mg/cu.m.

Table 3. Summary of Toxicological Dose and Endpoints for Ammonia [1]

Occupational Exposure Scenario	Dose Used in Risk Assessment	Target Margin of Exposure (MOE) for Occupational Exposure	Study and Toxicological Effects
Dermal (all durations)	A dermal endpoint was not selected. Labels will specify the use of gloves, full body clothing and eye protection. Closed delivery systems negate dermal contact with chemical during Mixing/Loading/Application.		
Inhalation (all durations)	8-hr TWA NOAEL= 6.4 mg/m^3 (9.2 ppm) 24-hr adjusted NOAEL (HEC) = 2.3 mg/m^3 (3.3 ppm) (Continuous Occupational Exposure) [a] Inhalation RfC = 0.1 mg/m^3 (Lifetime Daily Exposure for General Population) [b]	LOC for MOE = 30 [c] Based on UF = 10X (intra-species extrapolation) and 3X (database deficiencies)	Occupational Study (Holness et al. 1989) LOAEL= none Lack of evidence of decreased pulmonary function or changes in subjective syptomatology. See IRIS record (USEPA 2005a) for more detailed discussion. [2]

Source: Review Memorandum, "Hazard Assessment for Ammonia and Monochloroamine" by D. Smegal, MPH, Toxicologist (DP Barcode D313637) dated December 9, 2005.

[1] *TWA = time-weighted average, UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, LOC=level of concern , MOE = margin of exposure, HEC= human equivalent concentration, RfC = reference concentration.*

[2] *U.S. EPA 2005a. Integrated Risk Information System for Ammonia.* http://www.epa.gov/iris/subst/0422.htm.

[a] The NOAEL of 6.4 mg/m^3 (9.2 ppm) from an occupational study is based on an 8-hour TWA and was selected based on lack of evidence of decreased pulmonary function or changes in subjective syptomatology in the occupational study (Holness et al. 1989). This NOAEL is adjusted to account for continuous occupational exposure as a human equivalent concentration (HEC) of 2.3 mg/m^{3}according to the following equation:

NOAEL (HEC) = 6.4 mg/m^3 × (MVho/MVh) × 5 days/7 days

Where: MVho is the breathing volume for an 8-hour occupational exposure (10 m^3); and
MVh is the breathing volume for a 24-hour continuous exposure (20 m^3).

A NOAEL (HEC) of 2.3 mg/m^3 is extrapolated to 3.3 ppm:
(where 1 ppm = 0.707mg/m^3 , so 2.3 mg/m^3 ÷ 0.707mg/m^3 = 3.3 ppm).

[b] The 24-hour adjusted NOAEL of 2.3 mg/m^3 is the basis of the Agency's inhalation reference concentration (RfC) presented on the Integrated Risk Information System (IRIS) and represents Agency consensus. Since ammonia is a respiratory irritant, the Agency believes that the irritation potential would limit exposure. The RfC represents an estimate of a daily inhalation exposure of the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime.

An inhalation RfC of 0.1 mg/m^3 is established as follows: RfC = NOAEL (HEC) ÷ UF

Where: NOAEL (HEC) = 2.3 mg/m^3 and UF = 30 (2.3/30 = 0.0766 rounded up to 0.1)

[c] An inhalation MOE of 30 is adequate for all durations. An uncertainty factor of 10 is used to allow for the protection of sensitive individuals (intra-species extrapolation). Because it is based on a human epidemiological study, no inter-species safety factor is required. A factor of 3 was used to account for several database deficiencies including the lack of chronic data, and the lack of reproductive and developmental toxicology studies.

cc: Doreen Aviado/RASSB/AD
Chemical/Circulation Files

Decision #: 352403

DATA PACKAGE BEAN SHEET

DP #: (313640)

Date: 08-Feb-2006

* * * Registration Information * * *

Registration: 1448-UGE - BCMW

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# CM-2 308B

Risk Manager Reviewer: Norman Cook NCOOK

Sent Date: _____ Calculated Due Date: 08-Apr-2006 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A46) NEW USE;WITH EXEMPTION;NEW FOOD USE;

Ingredients: 005302, Ammonia(7.59%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 22-Feb-2005 Due Back: _____

DP Ingredient: 005302, Ammonia

DP Title: _____

CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #: 313224

Assigned To		Date In	Date Out		
Organization:	AD / RASSB	22-Feb-2005	08-Feb-2006	Last Possible Science Due Date:	24-Nov-2005
Team Name:	RASSB2	22-Feb-2005	01-Feb-2006	Science Due Date:	
Reviewer Name:	Aviado, Doreen	22-Feb-2005	01-Feb-2006	Sub Data Package Due Date:	
Contractor Name:					

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Sub-bean for human exposure/MOE assmt. NCook

DP#: (313640) *** Additional Data Package for this Decision *** Decision#: (352403)

DP #	Division/Branch	Date Sent	Date Due	Instructions?	CSF	label
313221	AD / RMB1	14-Feb-2005	08-Mar-2006	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313221	AD / PSB	14-Feb-2005	08-Mar-2006	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313223	AD / RMB1	14-Feb-2005	08-Mar-2006	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313223	AD / PSB	14-Feb-2005	08-Mar-2006	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313224	AD / RMB1	14-Feb-2005	24-Nov-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313224	AD / RASSB	14-Feb-2005	24-Nov-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313637	AD / RASSB	22-Feb-2005	24-Nov-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313637	AD / RASSB	22-Feb-2005	24-Nov-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313638	AD / RASSB	22-Feb-2005	24-Nov-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313638	AD / RASSB	22-Feb-2005	24-Nov-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
321768	AD / RMB1	21-Sep-2005	13-Jan-2005	○ Yes ○ No	● Yes ○ No	● Yes ○ No
321768	AD / PSB	21-Sep-2005	13-Jan-2005	○ Yes ○ No	● Yes ○ No	● Yes ○ No

APPENDIX A:

Description and Schematic of *BUSAN 1215* Chemical Feed Skid

Buckman Laboratories, Inc. submitted data on product use (Series 875 GLN 875.1700 and 875.2700) and description of human activities (Series 875 GLN 875.2800) for *BCMW/BUSAN 1215* as provided in the Supplemental Report *"Mammalian Toxicology and Environmental Fate and Effects Data"* (MRID. 464581-01) received January 31, 2005. An excerpt on the dedicated *BUSAN 1215* feed equipment follows:

"BUSAN 1215 is [redacted] The product is designed to be mixed with sodium hypochlorite (12% a.i. source) added through a carefully designed chemical feed skid that allows the two to mix and form monochloramine. The chemical feed skid is designed to allow the introduction of *BUSAN 1215* to a pipe where there is continuous flow through dilution water available. The additional dilution of the product is insured by sending the product and dilution water through an in-line mixer so that the hypochlorite and ammonia mixture will react to form monochloramine before being sent to its intended treatment location.

The chemical feed system has been designed to incorporate numerous safety features that include:

- Double walled chemical dosing lines;
- Position and size of installation connections to mother/daughter chemical tanks make it impossible to mix the chemicals external to the unit;
- Degassing lines on the outside of the unit to prevent bleach from decomposing and gassing;
- Safety shower on unit;
- Lock on unit door to prevent unauthorized entry;
- Removal of door panels on front/back to give access to all internal pumps, valves, etc..;
- Removable spill containers under all connection locks;
- Multiple shut off alarms and switches are included to prevent any unsafe condition.

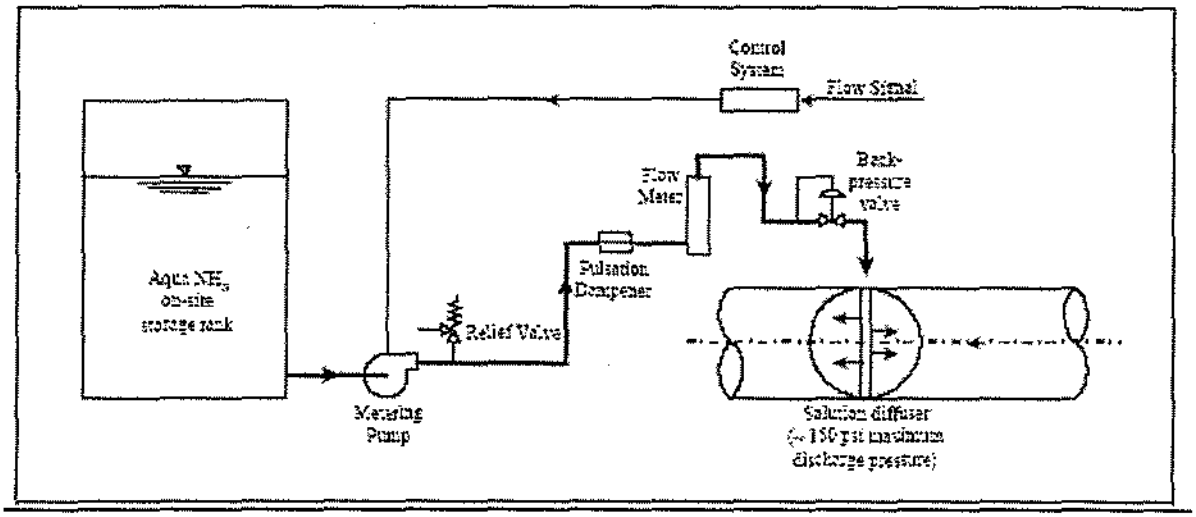
For example, the following will put the unit in alarm mode:

external or internal power failure,
internal leak detection sensor activated,
insufficient dilution water flow sensor,
external manual emergency shut off switch,
low chemical detection sensors.

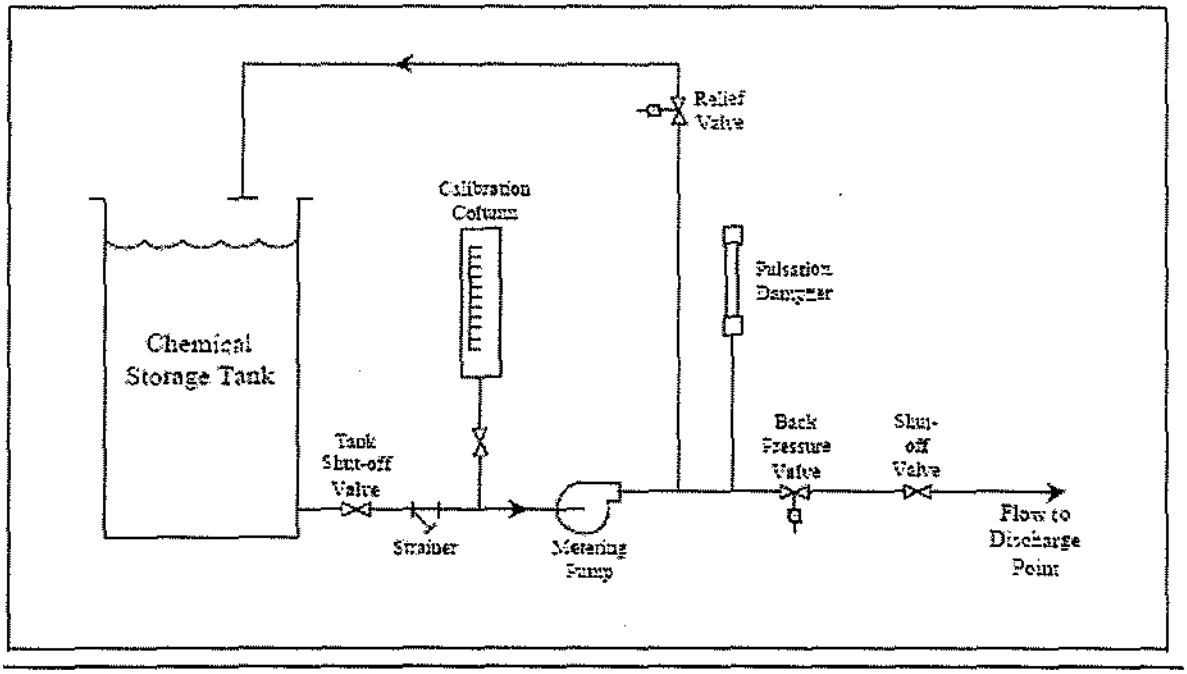
When an alarm condition is evident, the unit stops feeding chemicals and automatically flushes all chemical feed lines with fresh water so that no storage hazards will exist. The valves that control the fresh water flush are pneumatically operated by an attached pressurized air tank so that the unit will be able to shut down safely should a power outage occur."

Inert ingredient information may be entitled to confidential treatment

Generic Chemical Feed System Schematic for Water Treatment



Aqueous Ammonia Feed System



Hypochlorite Feed System

Source "Alternative Disinfectants and Oxidants Guidance Manual." US EPA, Office of Water, EPA 815-R-99-014. April 1999.

Page 87 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

✓ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-Client work product.

_____ Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 9, 2006

SUBJECT: Buckman Laboratories has submitted an application for registration of the product, Busan 1215/BCMW, for the manufacture of paper and paperboard products

FROM: Robert Quick, Chemist
Risk Assessment and Science Support Branch
Antimicrobials Division (7510C)

TO: Velma Noble, Product Manager Team 31
Regulatory Management Branch I
Antimicrobials Division (710C)

THRU: Norm Cook, Chief
Risk Assessment and Science Support Branch
Antimicrobials Division (7510C)

ID#: 1448-UGG-Busan 1215

DP BARCODE: D313228, D313639

DECISION NO.: 352404

PC CODE: 005302

CHEMICAL NAME: Ammonia

CAS#: 7664-41-7

MRID#s: 464405-00, 464580-01, 464581-01

Introduction:

Buckman Laboratories has submitted an application for registration of the product, BUSAN 1215, for use in influent water systems and all process water systems used for the manufacture of paper and paperboard products.

The label for this product lists ammonia as the active ingredient. The "bean sheets" list ammonia as the active ingredient.

The CAS No. for ammonia is 7664-41-7 and for [redacted]

Under the conditions of the proposed use, addition of hypochlorous acid to the Busan 1215 product, monochloramine (chloramine) is formed. The active ingredient resulting from the proposed use is chloramine.

Chloramine does not appear to have a clearance from the FDA for use as a slimicide.

Background:

Ammonia is exempt from the requirement of a tolerance when used after harvest on the raw agricultural commodities grapefruit, lemons oranges and corn for feed use only (40 CFR 180.1003).

Ammonia is also used as a fertilizer injected into fields of growing crops.

Ammonia-related chemicals are cleared by the Food & Drug Administration (FDA) in the CFR, including 21 CFR 176.170.

Chloramine is permitted in bottled water as a residual disinfectant under 21 CFR 165.110(H) at a level of 4 ppm as Cl2.

Chloramine has been used for disinfection in the United States since the early 1900s.

There is no clearance by the FDA for the use of chloramines in paper-making.

See Confidential Appendix for further discussion.

Conclusions:

1. The residues in paper resulting from the proposed use are expected to be chloride ions, sulfate ions and chloramine.

2. The residues in paper mill effluent water resulting from the proposed use are expected to be chloride ions, sulfate ions and chloramines.

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3. Chloramine residues in effluent can be eliminated through the addition of sodium bisulfite to the effluent water.

4. An analytical method is available to detect chloramine residues in effluent water.

5. The dietary contribution from the proposed use is 4.6 ppbas residues from the proposed pulp and paper use.

6. For a 70 kg male, this would result in a dietary intake of 0.00020 mg a.i./kg body wt/day from the proposed use.
For a 60 kg female, this would result in a dietary intake of 0.00023 mg a.i./kg body wt/day from the proposed use.
For a 15 kg child, this would result in a dietary intake of 0.00046 µg. a.i./kg body wt/day from the proposed use.

7a. AD determined that there were no effects attributable to a single dose for the acute dietary risk (Deborah Smegal memo dated 12/9/2005).
b.Utilizing the chronic RfD or cPAD of 0.1 mg/kg day taken from the Deborah Smegal memo, the dietary risk were estimated for chloramine as:
0.20% (adult male)
0.23 % (adult female)
0.46% (child)

Thus, the Agency concludes that dietary exposure to monochloramine from the pulp and paper use of Busan 1215 does not exceed the Agency's level of concern.

8. The paper making process is an indoor use. A hydrolysis study is a data requirement for an indoor use. No hydrolysis study is submitted. A literature reference states that chloramine hydrolyzes slowly in aqueous solution. A hydrolysis study must be submitted. Depending on the results of the hydrolysis study, a photodegradation study in water may be needed.

Recommendations:

1. There are no dietary exposure issues remaining for the proposed use in this submission.

2. For environmental fate, the registrant must address the deficiency stated in conclusion 8 above. For this reason, RASSB cannot recommend for the registration of this product in the water systems of paper mills at this time.

3. Chloramine does not appear to have a clearance from the FDA for its use as a slimicide. Chloramine is not an ingredient in the formulation, but is present as a result of a chemical reaction between the product when it is used in conjunction with sodium hypochlorite (12.5%) to form monochloramine. RMB I should discuss with the FDA whether chloramine should be cleared by the FDA for use as a slimicide.

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DBARCODE 313639 Dietary Exposure Assessment

Detailed Considerations

OPPTS GLN 860.1100 Chemical Identity

Chemical	Empirical Formula	Molecular Weight
Ammonia CAS# 7664-41-7	NH_3	17.02
Chloramine CAS# 10599-90-3	ClH_2N	51.48

See Confidential Appendix for further discussion of the CSF.

OPPTS GLN 860.1200 Proposed Use

The product is for use in controlling algal, bacterial and fungal deposits in influent water systems, and all process water systems used in the manufacture of paper and paperboard products.

The product will be used in conjunction with sodium hypochlorite (12.5%) to form monochloramine, also known as chloramine.

RASSB understands from the label that the use is as a slimicide.

The products are added to dilution water to achieve a minimum molar ratio of 1.5 : 1 of ammonia to oxidant. This is done by combining 0.6 fl. oz of Busan 1215 to 1 fl. oz of sodium hypochlorite (12.5%). The monochloramine generated is to be fed into the treatment water systems through a feed skid only by a trained Buckman representative.

When the system is noticeably fouled, the total chlorine residual should be at least 1 ppm in excess of the system oxidant demand. When fouling control is obtained, treatment rates can be reduced to 50-80% of system demand. The product can be administered to the system either continuously or intermittently in any part of the system where mixing can be obtained. Chloramine is formed in line prior to being added to the pulp and paper water system.

The label does not propose application rate in term of lbs. active ingredient per ton of paper produced. The registrant was requested to propose dosage in those terms by RMB I. The registrant response in the Carl Watson (Buckman) e-mail dated 12/14/2005 to Drusilla Copeland (RMB I) states that, "Recommended application rate is limited to 2 ppm over system demand (oxidant demand) not to exceed 5 ppm total treatment rate".

For purposes of the review and based on the Buckman e-mail, RASSB will assume that the registrant is proposing that 5 ppm of chloramine is to be present in the paper mill water that is used in the production of paper.

The treatment can be repeated as necessary.

RASSB has perused the internet and has founds two references citing the quantity of water used to produce a ton of paper. The reference, http://64.233.161.104/search?q=cache:Gc7TGk9BiRUJ:wwwnarmada.org/related.issues/ka...), states that, "the average water consumption used in US paper mills was around 75 kiloliter (KL) per ton in 1995". One kiloliter of water is equivalent to 264.2 US gallons.

A Weyerhaeuser Company paper entitled, "Conserving Environmental Policy", states that, "Since 1980, Weyerhaeuser has reduced the amount of water required to produce a ton of pulp or paper by 58%-from 25,900 gallons to 11,000 gallons". One Weyerhaeuser plant has reduced its water consumption to 8800 gallons per ton of paper. It is unlikely that all paper producers have reduced the gallons of water used to produce a ton of paper. For purposes of this review RASSB will use the figure of 25,000 US gallons of water per ton of paper produced.

If chloramine is detected in the effluent, sodium meta bisulfite can be added until the chloramine is no longer detected. Note: This part of the use directions appears to assume that the system effluent is monitored.

OPPTS GLN 860.1340 Nature of the Residue

Chloramine is formed by the reaction of ammonia and sodium hypochlorite under alkaline conditions (Wipedia org.).

Chloramine is a disinfectant produced by combining chlorine and ammonia at a weight of 5:1 or slightly less. Monochloramine is the dominant compound formed and is generally considered to be a suitable disinfectant. The term chloramine generally refers to monochloramine. In general, almost all chloramine is monochloramine with insignificant amounts of dichloramine and trichloramine under conditions of water treatment and distribution. (San Francisco Public Utilities Commision).

Chloramines are weaker disinfectants than chlorine, but are more stable. Since chloramines are not as reactive as chlorine with organic matter in water, they produce substantially lower concentrations of disinfection by-products in the distribution system. Some disinfection byproducts, such as trihalomethane (THMs) and haloacetic acids (HAAs) may have adverse health problems at high levels. EPA recently reduced the allowable Maximum Contaminant Levels for total THMs to 80 µg/L and now limit HAAs to 60 µg/L. The use of chlorine and chloramines is also regulated by the EPA. There are maximum Residual Disinfectant levels of 4.0 mg/L for both of these disinfectants. (EPA Region 9: Water Programs)

Chloramine is a colorless, unstable, pungent liquid; soluble in water; decomposes (slowly in dilute solution) to form nitrogen plus hydrochloric acid and ammonium chloride. (Hawley Chemical Dictionary)

Chloramine: "It is stable as a gas or in solutions but the liquid and solid are explosive. The chlorination of aqueous NH_3 has been studied in detail and NH_2Cl is readily obtained by interaction of NH_3 and OCl^- at pH > 8." (Advanced Inorganic Chemistry, Fifth Edition, FAlbert Cotton and Geoffrey Wilkinson, page 332)

Chloramine decomposes by hydrolysis to form ammonia and hypochlorous acid. The half life depends on various environmental factors. The half life has been found to be about ten hours (Environment Canada: Chlorinated Water Effluents).

The label for this product claims that the active ingredient is ammonia. See Confidential Appendix for further discussion.

The proposed use involves the mixing of hypochlorous acid and the product BUSAN 1215 in a pulp and paper plant. The combination of these two formulations produces chloramine which is the oxidizing microbiocide intended to provide algal, bacterial and fungal control in the water systems used for the manufacture of paper and paperboard products.

Chloramine is consumed during the paper making process when it controls the algal, bacterial and fugal growth. Any residue occurring in paper from the microbiocide treatment would be expected to be residual chloride ion and chloramine. During the production of paper sheet, the sheet moves into a drying section where it comes into steam-heated cylinders. Chloramine is a somewhat stable chemical, but is sensitive to bacteria, light and heat.

Chloramine would be expected to be partially degraded during the paper making process. The rolling of paper into sheets and the squeezing of water from the sheet at elevated temperature is likely to degrade a portion of residual chloramine.

See Confidential Appendix for comments on the expected degradation products of chloramine starting materials.

Testing of the effluent water (white water) from the paper plant for excess chloramine can be carried out using a test kit for chloramine. If chloramine is present, sodium bisulfite is to be added to the effluent water to destroy the chloramines. This step should greatly reduce the level of chloramines in discharge water from the paper pulp plant.

The reaction is:

$$NH_2Cl + HSO_3^- + H_2O \rightarrow NH_4^+ + Cl^- + SO_4^{=} + H^+$$

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After discharge from the paper pulp plant, the discharge water is usually held in a lagoon before discharge into waterways. The typical measurements for such lagoons are approximately one-forth mile wide and one-half mile long. The discharge water from paper mills typically are retained in the lagoons for several days. The pH in lagoon water is typically 7 or higher. Any remaining chloramines in the paper mill discharge water would be expected to be further degraded during this time period. No hydrolysis data are available for chloramines. A hydrolysis study must be submitted.

OPPTS GLN 860.1340 Residue Analytical Method

Chloramine:

Berthelot reaction: Chloramine in paper mill wastewater can be detected using a colorimetric technique. Chloramine is reacted with excess phenol in an alkaline solution to form the colored dye, Indophenol Blue. It is commercially available test kits. Chloramine levels of ≥ 0.1 ppm can be determined in water.

Ammonia:

Many of the methods used for environmental ammonia samples are methods approved by Federal Agencies such as EPA, and NIOSH. Methods are also available from the AOAC and the APHA.

OPPTS GLN 860.1500, Magnitude of the Residue

A portion of the chloramine residue in the paper mill treatment water would be expected to be destroyed during algal, bacterial and fungal control in the mill water.

If a chloramine residue remains in the treatment water and survives the heating process in making of paper sheet, a major portion of the chloramine residue would likely be squeezed into the waste water during the sheet process (Chloramine is water soluble and 99-99.5% of the chloramine residue in the wet paper pulp would be squeezed from the paper sheet and either discharged into waste water (white water) or recycled through the paper mill process).

Using the Food & Drug Administration model (which assumes that a large portion of the antimicrobial in the mill water is lost in the discharge water (white water)) for paper makes a worst case for residues in paper that may contact food, maximum residues in paper can be calculated as follows:

- The application rate of oxidant (chloramine) in the water used in the paper making process is 5 ppm.
- 25,000 gallons of water is used to produce 1 ton of paper.
- 25,000 gallons of water weighs 208,500 lbs (8.34 lbs/gal x 25,000 gals) used per ton of paper produced.

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- 5ppm of chloramines in 208,500lbs of water used to produce 1 ton of paper is 1.0 lb of chloramine per ton of paper. (Calculation: 5 lbs/1,000,000 = x/200,000).
- Maximum rate of the chloramine application level applied to paper is 1.0 lbs. active/ton of paper of paper. Because paper pulp is diluted with water to make a paper slurry which is less than 1% paper pulp prior to entering the paper machine, the application rate for the chloramine chemical is equivalent to 5 ppm in the paper slurry. The paper slurry is 1 % paper pulp (from which the paper will be produced); then, this is equivalent 1.0lbs act./200,000 lbs of paper slurry or 5 ppm of the active ingredient in the paper slurry.

  Calculation: 1.0 lbs. act./2000 lbs of finished paper.

  Pulp paper is 1% of the paper slurry (the water/paper pulp mixture).
  2000 lbs paper pulp/0.01(the percentage of paper pulp in the slurry) = 200,000 lbs of slurry.

  Then 1.0 lbs active/200,000 lbs of slurry = 5 ppm of active in the paper slurry.
- Prior to entering the driers, the slurry consists of 33% pulp and 67% water. The application rate was further adjusted to account for the amount of pulp present in the finished paper.
- The finished paper (after paper making) contains 92% pulp and 8% water.
- The standard basis weight of paper is 50 mg/in^2.
- The amount of food contacting the paper packaging is 10 g of food/in^2 of paper.
- There is 100% migration of chloramine from the treated paper into food.
- Adult food consumption is 3 kg/day; child food consumption is 1.5 kg/day.
- Adult body weight is 70 kg for a male; 60 kg for a female and 15 kg for a child.

Calculations:

Determination of the application rate in terms of ai and finished paper is:

Application rate on label:

lbs ai/2000 lbs of finished paper

Pulp slurry (e.g., water/paper pulp mixture) is 1% pulp therefore,

2000 lbs paper/0.01 = 200,000 lbs of slurry

Conc. of ai in the pulp prior to entering the driers is:

Adjusted application rate x water/pulp ratio

(5.0 µg ai/g slurry water) x (67 g water/33 g pulp) = 10 µg ai/g pulp

Conc. of ai in the finished paper is:

Adjusted application rate x percentage of pulp in finished paper:

(10 µg ai/g pulp) x (0.92 g pulp /g finished paper) = 9.2 µg ai/g paper

Determination of dietary concentration:

App rate x Basis paperweight x Surface area contacting food x Consumption factor x % migration

(9.2 µg ai/g paper) (0.05 g paper/in^2 paper) (in^2 paper/10 g food) (0.1) (100%) =

0.0046 µg ai/g (ppm) in food or 4.6 ppb

Determination of the Estimated Daily Intake (EDI):

Dietary conc. x Daily food consumption

Adult: (0.0046 µg ai/g food) (3000 g food /day) = 13.8 µg ai/person/day

Child: (0.0046 µg ai/g food) (1500 g food /day) = 6.9 µg ai/person/day

Determination of the Daily Dietary Dose:

EDI / Body Weight

Adult male: (13.8 µg ai /day) (mg/1000 µg) / (70 kg) = 0.00020 mg ai/kg bw/day

Child: (6.9 µg ai/day) (mg/1000 µg) / (15 kg) = 0.00046 mg ai/kg bw/day

Adult female: (13.8 µg ai /day) (mg/1000 µg) / (60 kg) = 0.00023 mg ai/kg bw/day

TABLE 1

Cumulative Estimated Dietary Intake of Chloramine

Use	**Dietary Conc. (ppb)**	**Estimated Daily Intake (µg/person/day)**	**Daily Dietary Dose (mg/kg bw/day)**
Pulp/Paper	4.6	13.8 (male)	0.00020 (male)
Slimicide	4.6	13.8 (female)	0.00023 (female)
	4.6	6.9(child)	0.00046 (child)

There were no effects attributable to a single dose for the acute dietary risk (Deborah Smegal memo dated 12/9/2005).

Utilizing the chronic RfD or cPAD of 0.1 mg/kg day taken from the Deborah Smegal memo, the dietary risks were estimated and summarized in Table 2.

TABLE 2
Dietary Risks of
Chloramine

Use	**Daily Dietary Dose (mg/kg bw/day)**	**% aPAD**	**%cPAD**
Slimicide	0.00020 (adult M)	No effects	0.20% (adultM)
	0.00023 (adult F)	No effects	0.23 % (adultF)
	0.00046 (child)	No effects	0.46% (child)

%PAD = exposure/PAD x 100

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Thus, the Agency concludes that dietary exposure to monochloramine from the pulp and paper use of Busan 1215 does not exceed the Agency's level of concern.

US Food and Drug Administration (US FDA) Center for Food Safety & Applied Nutrition's (CFSAN). 2002. "Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations." http://www.cfsan.fda.gov/~dms/opa2pmnc.html. April.

DBARCODE D313228 Environmental Fate Assessment

The use of chloramine in pulp and paper mills is considered to be an indoor use under Part 158, Subpart W. For this use, the Agency requires a hydrolysis study.

No hydrolysis study is submitted. A literature reference states that chloramine hydrolyzes slowly in aqueous solution. Aeration and boiling of water are not effective for the removal of chloramine; a minimal aeration loss of 10-15 % has been reported for chloramine. Chloramine seem to be quite stable in sunlight. (http://dsp-psd. pwgsc.gc.ca/Collection/H48-10-1-25-1996.pdf).

A hydrolysis study must be submitted for chloramine. Depending on the results of the hydrolysis study, a photodegradation study in water may be needed.

A limited amount of data are available on the fate of chloramine in the environment. A statement in the paper entitled, "Monochloramine Decay in Model and Distribution System Waters" (PERGAMON, www.elsevier.com/locate/watres), page 1766, reads, "Unfortunately, in spite of the long history of chloramine use, the fate of chloramine in distribution systems and the characteristics and processes that influence their stability are largely unknown".

An aise.net.org. reference states that the acute ecotoxicity of chloramine (when expressed as NaOCl equivalents) is similar to hypochlorites.

RASSB also has the following additional comments for the occurrence of ammonia in the environment.

Ammonia

The following information is taken from the Buckman Laboratories submission.

Ammonia occurs widely in nature. It occurs in soil, water and air. It is present as both ammonia and as the ammonium ion (NH_4^+). It does not last long in the environment because it is recycled naturally.

Ammonia exists in air at levels between 1 and 5 ppb. In air, ammonia reacts with acid air pollutants. The half life of ammonia in the atmosphere has been estimated to be a few days. Estimates of the global concentration of ammonia in air are approximately 0.6-3 ppb. This will depend on whether urban or agricultural areas are nearby.

When ammonia occurs in water under normal aerobic conditions, it is usually present as nitrate.

If ammonia is released to surface water, it can volatilize to the atmosphere. The rate of volatilization depends on the temperature and on the pH.

Uptake of ammonia by fish can also occur under certain conditions (Hargreaves 1998; Mitz and Giesy 1985)

Ammonia is present in nature as a result of organic matter decay (plants, animals, animal manure). It is also synthetically produced.

The major use of ammonia in the U.S. is as a fertilizer injected into soil.

Ammonia is a plant nutrient. It is also a part of the nitrogen cycle. Excess nitrogen is phytotoxic to plants. Ammonia is important in nitrogen metabolism because it functions as a source in the synthesis of amino acids.

Aqueous and gaseous ammonia have been used to control microbial growth in stored fruits, hay and grains.

Ammonia is adsorbed on soil. In clay, the ion tends to be adsorbed on the negative adsorption sites of clay colloids. Under anaerobic conditions, the absorptive capacity of the soil is less, resulting in the release of ammonia to either the water column or an oxidized sediment layer.

Page 99 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

✓ Identity of product inert ingredients.

_____ Identity of product impurities.

✓ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-Client work product.

_____ Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Decision #: 352404

DATA PACKAGE BEAN SHEET

DP #: (313228)

Date: 17-Jan-2006

* * * Registration Information * * *

Registration: 1448-UGG - BUSAN 1215

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# CM-2 308B

Risk Manager Reviewer: Drusilla Copeland DCOPELAN

Sent Date: _____ Calculated Due Date: 08-Apr-2006 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A46.0) NEW USE;WITH EXEMPTION;NEW FOOD USE;

Ingredients: _____

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 14-Feb-2005 Due Back: _____

DP Ingredient: _____

DP Title: _____

CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #: _____

Assigned To		Date In	Date Out	
Organization:	AD / RASSB	22-Feb-2005	17-Jan-2006	Last Possible Science Due Date: 13-Jan-2005
Team Name:	RASSB1	22-Feb-2005	17-Jan-2006	Science Due Date:
Reviewer Name:	Quick, Bob	22-Feb-2005	17-Jan-2006	Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Please review the attached studies on ammoni. Scoping metting to be scheduled MRID# 46458001,46440501,46435105,46435106,46435107,46458100,46458101. New use pulp and paper manfacturing /food use.

DP#: (313228) *** Additional Data Package for this Decision *** Decision#: (352404)

DP #	Division/Branch	Date Sent	Date Due	Instructions?	CSF	label
313226	AD / RMB1	14-Feb-2005	08-Mar-2006	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313226	AD / PSB	14-Feb-2005	08-Mar-2006	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313227	AD / RMB1	14-Feb-2005	10-Jun-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313227	AD / PSB	14-Feb-2005	10-Jun-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313639	AD / RASSB	22-Feb-2005	13-Jan-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313639	AD / RASSB	22-Feb-2005	13-Jan-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
321671	AD / RMB1	14-Sep-2005	13-Jan-2005	○ Yes ○ No	● Yes ○ No	● Yes ○ No
321671	AD / PSB	14-Sep-2005	13-Jan-2005	○ Yes ○ No	● Yes ○ No	● Yes ○ No

Decision #: 352403

DATA PACKAGE BEAN SHEET

DP #: (313638)

Date: 17-Jan-2006

* * * Registration Information * * *

Registration: 1448-UGE - BCMW

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# CM-2 308B

Risk Manager Reviewer: Norman Cook NCOOK

Sent Date: _____ Calculated Due Date: 08-Apr-2006 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A46) NEW USE;WITH EXEMPTION;NEW FOOD USE;

Ingredients: 005302, Ammonia(7.59%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 22-Feb-2005 Due Back: _____

DP Ingredient: 005302, Ammonia

DP Title: _____

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: 313224

Assigned To		Date In	Date Out	
Organization:	AD / RASSB	22-Feb-2005	17-Jan-2006	Last Possible Science Due Date: 24-Nov-2005
Team Name:	RASSB I	22-Feb-2005	17-Jan-2006	Science Due Date: _____
Reviewer Name:	Smegal, Deborah	22-Feb-2005	17-Jan-2006	Sub Data Package Due Date: _____
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Sub-bean for dietary risk assml. NCook

DP#: (313638) *** Additional Data Package for this Decision *** Decision#: (352403)

DP #	Division/Branch	Date Sent	Date Due	Instructions?	CSF	label
313221	AD / RMB1	14-Feb-2005	08-Mar-2006	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313221	AD / PSB	14-Feb-2005	08-Mar-2006	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313223	AD / RMB1	14-Feb-2005	08-Mar-2006	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313223	AD / PSB	14-Feb-2005	08-Mar-2006	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313224	AD / RMB1	14-Feb-2005	24-Nov-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313224	AD / RASSB	14-Feb-2005	24-Nov-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313637	AD / RASSB	22-Feb-2005	24-Nov-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313637	AD / RASSB	22-Feb-2005	24-Nov-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313640	AD / RASSB	22-Feb-2005	24-Nov-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313640	AD / RASSB	22-Feb-2005	24-Nov-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
321768	AD / RMB1	21-Sep-2005	13-Jan-2005	○ Yes ○ No	● Yes ○ No	● Yes ○ No
321768	AD / PSB	21-Sep-2005	13-Jan-2005	○ Yes ○ No	● Yes ○ No	● Yes ○ No

Decision #: 352404

DATA PACKAGE BEAN SHEET

DP #: (313639)

Date: 17-Jan-2006

* * * Registration Information * * *

Registration: 1448-UGG - BUSAN 1215

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# CM-2 308B

Risk Manager Reviewer: Norman Cook NCOOK

Sent Date: _____ Calculated Due Date: 08-Apr-2006 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A46.0) NEW USE;WITH EXEMPTION;NEW FOOD USE;

Ingredients: _____

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 22-Feb-2005 Due Back: _____

DP Ingredient: _____

DP Title: _____

CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #: 313228

Assigned To		Date In	Date Out	
Organization:	AD / RASSB	22-Feb-2005	17-Jan-2006	Last Possible Science Due Date: 13-Jan-2005
Team Name:	RASSB1	22-Feb-2005	17-Jan-2006	Science Due Date: _____
Reviewer Name:	Quick, Bob	22-Feb-2005	17-Jan-2006	Sub Data Package Due Date: _____
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Sub-bean for dietary exposure assmt. NCook

Cy

DP#: (313639) *** Additional Data Package for this Decision *** Decision#: (352404)

DP #	Division/Branch	Date Sent	Date Due	Instructions?	CSF	label
313226	AD / RMB1	14-Feb-2005	08-Mar-2006	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313226	AD / PSB	14-Feb-2005	08-Mar-2006	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313227	AD / RMB1	14-Feb-2005	10-Jun-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313227	AD / PSB	14-Feb-2005	10-Jun-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313228	AD / RMB1	14-Feb-2005	13-Jan-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
313228	AD / RASSB	14-Feb-2005	13-Jan-2005	○ Yes ○ No	○ Yes ● No	○ Yes ● No
321671	AD / RMB1	14-Sep-2005	13-Jan-2005	○ Yes ○ No	● Yes ○ No	● Yes ○ No
321671	AD / PSB	14-Sep-2005	13-Jan-2005	○ Yes ○ No	● Yes ○ No	● Yes ○ No

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
October 25, 2005

MEMORANDUM

Subject: Aqueous Ammonia (Busan 1215) Review of Ecological Effects Studies in Support of Registration

To: Drusilla Copeland, RMT 31
Velma Noble, RM 31
Regulatory Management Branch I
Antimicrobials Division 7510C

From: Kathryn Montague, Biologist
Risk Assessment and Science Support Branch
Antimicrobials Division (7510C)

Thru: Siroos Mostaghimi, Team Leader
Norm Cook, Branch Chief
Risk Assessment and Science Support Branch
Antimicrobials Division (7510C)

Buckman Laboratories, Inc., has submitted several ecological effects studies in support of registration of Busan 1215, a product containing 7.59% aqueous ammonia, for use in pulp and paper manufacturing. The results of those studies are summarized below.

1. **Gallagher, Sean P., and Joanne B, Beavers. 2004. BSN 1215: An Acute Oral Toxicity Study with the Northern Bobwhite. MRID #464405-01.**

The birds were dosed with levels of Busan 1215, which contains 7.6% total ammonia as the active ingredient (a.i.)] at levels ranging from 292 to 2250 mg/kg. No mortality or other effects were observed at any treatment level. The LD50 is therefore >2250 mg/kg (>171 mg ai/kg), indicating that the formulated product is practically non-toxic to bobwhite on an acute oral basis. The NOEL was 220 mg/kg (171 mg ai/kg). The study is acceptable for a formulated product test; however, no explanation was included as to why a TGAI (using >80% a.i.)acute oral test was not conducted. The TGAI test is still required for registration of Busan 1215, unless adequate justification for performing the test only with formulated product is submitted.

2. **Palmer, Susan J., Timothy Z. Kendall, and Henry O. Kreuger. 2004. Aqueous Ammonia Solution: A 96-Hour Flow-Through Acute Toxicity Test with the Bluegill (*Lepomis macrochirus*). MRID #464351-05.**

Bluegill were exposed to measured concentrations of aqueous ammonia ranging from 14 to 117 mg a.i./L. No mortalities or other effects were observed at any treatment level. The LC50 was therefore >117 mg/a.i./kg, indicating that aqueous ammonia is practically non-toxic to bluegill on an acute basis. The NOEC was 117 mg a.i./L. The study is acceptable, and fulfills OPPTS Guideline 850.1075/72-1a.

3. **Palmer, Susan J., Timothy Z. Kendall, and Henry O. Kreuger. 2004. Aqueous Ammonia Solution: A 96-Hour Flow-Through Acute Toxicity Test with the Rainbow Trout (*Oncorhynchus mykiss*). MRID #464351-06.**

Rainbow trout were exposed to measured concentrations of aqueous ammonia ranging from 15 to 126 mg a.i./L. No mortalities or other effects were observed at any treatment level. The LC50 was therefore >126 mg/a.i./kg, indicating that aqueous ammonia is practically non-toxic to rainbow trout on an acute basis. The NOEC was 126 mg a.i./L. The study is acceptable, and fulfills OPPTS Guideline 850.1075/72-1c.

4. **Palmer, Susan J., Timothy Z. Kendall, and Henry O. Kreuger. 2004. Aqueous Ammonia Solution: A 48-Hour Flow-Through Acute Toxicity Test with the Cladoceran (*Daphnia magna*). MRID #464351-07.**

Daphnids were exposed to measured concentrations of aqueous ammonia ranging from 14 to 120 mg a.i./L. No mortalities or other effects were observed at any treatment level. The LC50 was therefore >120 mg/a.i./kg, indicating that aqueous ammonia is practically non-toxic to daphnids on an acute basis. The NOEC was 120 mg a.i./L. The study is acceptable, and fulfills OPPTS Guideline 850.110/72-2a.

Based on the intended use pattern of Busan 1215 and the low toxicity demonstrated in these studies, no further ecological effects testing is required for the currently proposed uses, with the exception of a TGAI avian acute oral test or adequate justification for using only the formulated product test.

Review of Environmental Labeling for Busan 1215

The Environmental Hazards section of this label is acceptable for fish and aquatic organisms in its current form. A statement regarding avian toxicity may need to be added, pending results of the TGAI avian acute oral study.

Environmental and Ecological Risk of Bellacide 350

Busan 1215 is an antimicrobial intended for use to control algae, bacteria, and fungi in pulp and paper mill influent and process water systems. Busan 1215 is used in conjunction with sodium

hypochlorite to form monochloramine, which is the actual oxidizing agent exerting microbiocidal action in the treated system. Facilities using Busan 1215 are required to have NPDES permits before discharging effluents into receiving waters. Additionally, the label directs the user to neutralize any detected chloramine in the effluent by adding sodium meta bisulfite until the chloramine is no longer detected. Due to low environmental exposures, adverse effects on terrestrial and aquatic species are not anticipated.

Listed Species

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA, 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg. 81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a "no effect" determination. The pulp and paper mill uses of Busan 1215 fall into this category.

If you have any questions on the above, please contact Kathryn Montague (703-305-1243 or montague.kathryn@epa.gov).

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DATA EVALUATION RECORD
AVIAN ACUTE ORAL TOXICITY TEST
GUIDELINE OPPTS 850.2100

1. **CHEMICAL:** Aqueous Ammonia **PC Code No.: 005302**

2. **TEST MATERIAL:** BUSAN 1215 **Purity:** 7.6% (total) ammonia
   Aqueous Ammonia Solution
   Batch/Lot Number 01
   Wildlife International, Ltd. ID No. 6771

3. **CITATION**

Authors:	Sean P. Gallagher Joann B. Beavers
Title:	BSN 1215: An Acute Oral Toxicity Study with the Northern Bobwhite
Study Completion Date:	December 22, 2004
Laboratory:	Wildlife International, Ltd. 8598 Commerce Drive Easton, Maryland 21601
Sponsor:	Buckman Laboratories International 1256 N. McLean Blvd. P.O. Box 80305 Memphis, Tennessee 38108-0305
Laboratory Report ID:	Wildlife International, Ltd. Project No. 210-122
MRID No.:	464405-01

4. **REVIEWED BY:** Kathryn V. Montague, Biologist US EPA/AD/RASSB
   Signature: Kathryn V Montague **Date:** 10/17/05

5. **APPROVED BY:** Siroos Mostaghimi, Team Leader US EPA/AD/RASSB
   Signature: Siroos Mostaghimi **Date:** 10/18/05

6. **STUDY PARAMETERS**

Scientific Name of Test Organism:	Northern Bowwhite (*Colinus virginianus*)
Age of Test Organism:	Approximately 24 weeks at test initiation
Definitive Test Duration:	October 22, 2004-November 5, 2004 (15 days)
Type of Concentrations:	Nominal

7. CONCLUSIONS

Results Synopsis:

LD_{50}:	>2250 mg/kg bw
No Mortality Concentration:	2250 mg/kg bw
NOEC:	2250 mg/kg bw

Verified Results Synopsis:

Results verified by visual inspection. There were no effects observed at any treatment level.

8. ADEQUACY OF THE STUDY

A. Classification: Acceptable (Core)

B. Rationale: No significant deviations from Guideline requirements.

C. Repairability: N/A

9. GUIDELINE DEVIATIONS

The following guideline deviations were based on EPA OPPTS Guideline 850.2100:

- Birds were housed in a cage with a ceiling height that ranged from 20 to 25 cm. The guideline states that the height for bobwhites should be at least 24 cm.
- Ventilation information was not provided.
- The average relative humidity averaged 43% ± 9%. The guideline states that humidity should be between 45% to 70%.
- A range-finding test was not specified; test dosage was established on toxicity information provided by the sponsor.

10. SUBMISSION PURPOSE: Registration

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species: • A wild waterfowl species, preferably the mallard (*Anas platyrhynchos*), or an upland game bird species, preferably the bobwhite (*Colinus virginianus*).	• Northern bobwhite (*Colinus virginianus*) (p. 8)
Age at beginning of test: • At least 16 weeks old.	• Birds were 24 weeks old (p. 8)
Supplier	• K& L Quail 26 Thompson Flat Road Oroville, CA 95965 (p.8)
Acclimation period: • At least 15 days.	• Birds were acclimated for 7 weeks (p. 9)

B. Test System

Guideline Criteria	Reported Information
Pens • Tests should be conducted indoors • Wire mesh should be used for floors and external walls • Floor areas should be at least 500 cm^2 per bird for bobwhite and 1,000 cm^2 per bird for mallard • Height of pens should be at least 24 cm for bobwhite and 32 cm for mallard	• Birds housed indoors (p.12) • External walls, ceilings, and floors constructed of wire mesh (p.12) • Pen floor space measured 3978 cm^2 (contained 5 birds in each pen: ~800 cm^2 floor area per bird) • Ceiling height measured 20 to 25 cm (p.12)
Test Conditions • Temperature held between 15 and 27°C • Photoperiod: 8-h light, 16-h dark is recommended. • Ventilation: should be sufficient to supply 10 to 15 air changes per hour • Relative humidity: 45 to 70% (higher is appropriate for waterfowl)	• Birds were housed at ambient temperature: average = 22.8°C ± 0.4°C (p.12) • Photoperiod: 8-h light, 16-h dark (p.12) • Ventilation information not provided • Average relative humidity 43% ± 9% (p. 12)
Diet was nutritious and appropriate for species?	• Yes, throughout acclimation and testing all birds fed game bird ration formulated to Wildlife International, Ltd.'s specifications by Cargill Animal Nutrition (p.11)

Guideline Criteria	Reported Information
Feed withheld at least 15 hours prior to dosing?	• Birds fasted 18 hours prior to dosing (p.11)

C. Test Design

Guideline Criteria	Reported Information
Range finding test • Should be conducted • Groups of a few birds administered 3 to 5 widely spaced doses (suggested: 2, 20, 200, and 2,000 mg/kg body weight)	• Specific information on a range-finding test not provided • Test dosage was established based upon toxicity information provided by the sponsor (p. 9)
Definitive Test • Nominal concentrations: At least five, in a geometric scale, unless LD_{50} > 2000 mg ai / kg.	• Five nominal doses at 292, 486, 810, 1350, and 2250 mg/kg bw were used (p.9) • Dosage was 40% of the next highest concentration (p. 9)
Controls: • Water control or vehicle control (if vehicle is used)	• Vehicle control: deionized water (p.11)
Number of birds per group: • 10 (strongly recommended)	• Testing conducted on ten birds per group, five male and five female (p.11)
Vehicle: • Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	• Deionized water (p.11)
Amount of vehicle per body weight: • Constant volume/weight % of body weight, not to exceed 1% (1ml/100g).	• 4 mL/kg bw (p. 19)
Observations period: • At least 14 days.	• 14 days (p. 12)

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	• Yes (p.3-4)

Guideline Criteria	Reported Information
Individual body weights measured at beginning of test, on day 14 and at end of test if extended beyond 14 days?	• Yes, body weights were measured individually at initiation and on days 3,7, and 14 of the test. (p. 10)
Mean feed consumption measured at beginning of test, on day 14, and at end of test if extended beyond 14 days?	• Yes, feed consumption was averaged from days 0-3, 4-7, and 8-14. (p. 10)
Control Mortality: • Not more than 10%	• There were no mortalities in the control group. (p. 13)
Raw data included?	• Yes (p. 15 and on)
Signs of toxicity (if any) were described?	• No signs of toxicity

Dose Response

Mortality

Dosage (mg/kg)	No. of Birds	Cumulative Number of Dead							
		Day of Study							
		1	2	3	4	5	6-8	9-11	12-14
Control	10	0	0	0	0	0	0	0	0
292	10	0	0	0	0	0	0	0	0
486	10	0	0	0	0	0	0	0	0
810	10	0	0	0	0	0	0	0	0
1350	10	0	0	0	0	0	0	0	0
2250	10	0	0	0	0	0	0	0	0

Symptoms

Dosage (mg/kg)	No. of Birds	Cumulative Number of Dead							
		Day of Study							
		1	2	3	4	5	6-8	9-11	12-14
Control	10	AN	AN	AN	AN	AN	AN	AN	AN

Dosage (mg/kg)	No. of Birds	Cumulative Number of Dead							
		Day of Study							
		1	2	3	4	5	6-8	9-11	12-14
292	10	AN	AN	AN	AN	AN	AN	AN	AN
486	10	AN	AN	AN	AN	AN	AN	AN	AN
810	10	AN	AN	AN	AN	AN	AN	AN	AN
1350	10	AN	AN	AN	AN	AN	AN	AN	AN
2250	10	AN	AN	AN	AN	AN	AN	AN	AN

AN = appear normal (no symptoms of toxicity observed)

Statistical Results

Statistical Method:

Statistical calculation of the LD_{50} values were not performed due to the absence of mortality in any of the treatment groups during the test. Therefore, the LD_{50} value was estimated to be greater than the highest concentration tested. No statistical analyses were conducted in order to calculate mean responses for treatment groups for food consumption and body weight. The no mortality concentration and the NOEC were determined by visual interpretation of the mortality and observation data.

Results Synopsis:

LD_{50}:	>2250 mg/kg bw
No Mortality Concentration:	2250 mg/kg bw
NOEC:	2250 mg/kg bw

13. VERIFICATION OF STATISTICAL RESULTS

Results were verified by visual inspection as there were no effects observed at any treatment level.

14. REVIEWER'S COMMENTS:

No additional comments

DATA EVALUATION RECORD
FISH ACUTE TOXICITY TEST, FRESHWATER AND MARINE
GUIDELINE OPPTS 850.1075

1. **CHEMICAL:** Aqueous Ammonia **PC Code No.: 005302**

2. **TEST MATERIAL:** Aqueous Ammonia **Purity:** 7.6% (total) ammonia
   BUSAN 1215, Batch/Lot number 1 (a,b,&c)

3. **CITATION**

   Author: Susan J. Palmer, B.S.
   Timothy Z. Kendall, M.S.
   Henry O. Krueger, Ph.D.

   Title: Aqueous Ammonia Solution: A 96-Hour Flow-Through Acute Toxicity Test with the Bluegill (*Lepomis macrochirus*)

   Study Completion Date: December 2, 2004

   Laboratory: Wildlife International, Ltd.
   8598 Commerce Drive
   Easton, Maryland 21601

   Sponsor: Buckman Laboratories International
   1256 N. McLean Blvd.
   P.O. Box 80305
   Memphis, Tennessee 38108-0305

   Laboratory Report ID: Wildlife International, Ltd. Project Number: 210A-103B

   MRID No.: 464351-05

4. **REVIEWED BY:** Kathryn V. Montague, Biologist US EPA/AD/RASSB

   Signature: Kathryn V. Montague **Date:** 10/17/05

5. **APPROVED BY:** Siroos Mostaghimi, Team Leader US EPA/AD/RASSB

   Signature: Siroos - Mostaghimi **Date:** 10/18/05

6. **STUDY PARAMETERS**

Scientific Name of Test Organism:	Bluegill (*Lepomis macrochirus*)
Age of Test Organism:	Juveniles
Definitive Test Duration:	96 Hours
Study Method:	Flow-through
Type of Concentrations:	Mean-measured

7. **CONCLUSIONS**

Results Synopsis:

96-hour LC50:	>117 mg/L
No Mortality Concentration:	117 mg/L
NOEC:	117 mg/L

Verified Results Synopsis:

Results were verified by visual inspection. There were no effects reported at any treatment level.

8. ADEQUACY OF THE STUDY

A. Classification: Acceptable (Core)

B. Rationale: No significant deviations from Guideline requirments

C. Repairability: N/A

9. GUIDELINE DEVIATIONS:

The following guideline deviations were based on EPA OPPTS Guideline 850.1075:

- The mean wet weight of the test organism was 0.29 g and ranged from 0.22 to 0.42 g. The guideline recommends a mean weight of 0.5 to 5.0 g.
- The pH of the water in the test chambers ranged from 8.3 to 8.5. The guideline states a preferred pH range of 7.2 to 7.6.
- The hardness of the dilution water was measured at 124 mg/L as $CaCO_3$ at test initiation. The guideline states a preferred hardness range of 40 to 48 mg/L as $CaCO_3$.

10. SUBMISSION PURPOSE: Registration

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species • Preferred species: bluegill sunfish (*Lepomis macrochirus*) or rainbow trout (*Oncorhynchus mykiss*)	• Yes, bluegill (*Lepomis macrochirus*) (P.10).
Mean Weight • 0.5-5 g	• Mean wet weight was 0.29 g and ranged from 0.22 to 0.42 g. (P. 8)
Mean Standard Length • Longest not > 2x shortest	• Yes. Mean total length was 3.3 cm and ranged from 3.0 to 3.7 cm. (P. 8)
Supplier	• Osage Catfisheries, Inc. Osage Beach, Missouri 65065 (P. 8)
All fish from same source?	• Yes. (P. 10)
All fish from the same year class?	• Yes. (P. 10)

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period • Minimum 14 days	• Yes, at least 14 days. (P. 11)
Wild caught organisms were quarantined for 7 days?	• Quarantine was not mentioned in the report. Fish were obtained from Osage Catfisheries, Inc.
Were there signs of disease or injury?	• The fish showed no signs of disease or stress. (P. 11)
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	• Not applicable. The fish showed no signs of disease or stress. (P. 11)
Feeding • No feeding during the study	• Bluegill were fed a commercially-prepared diet daily during the holding period. The fish were not fed for at least two days prior to the test or during the test. (P. 11)
Pretest Mortality • No more than 3% mortality 48 hours prior to testing	• Pretest mortality was not reported. The fish showed no signs of disease or stress. (P. 11)

C. Test System

Guideline Criteria	Reported Information
Source of dilution water • Soft reconstituted water or water from a natural source, not dechlorinated tap water	• Freshwater obtained from a well was used. (P. 11)
Does water support test animals without observable signs of stress?	• Percent mortality for the control was zero and the fish appeared normal. (P. 20)
Water Temperature • 12°C for cold water species • 17°C or 22°C for warm water species	• Target test temperature during the study was 22 ± 1°C. Temperatures ranged from 21.8 to 22.0°C. (P. 15, 18)
pH • Prefer 7.2 to 7.6	• Ranged from 8.3 to 8.5. (P. 18)
Dissolved Oxygen • Static: ≥ 60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs • Flow-through: ≥ 60%	• Ranged from 8.5 to 8.7 mg/L (≥ 98% of saturation). (P. 15, 18)
Total Hardness • Prefer 40 to 48 mg/L as $CaCO_3$	• Hardness of dilution water measured at 124 mg/L as $CaCO_3$ at test initiation. (P. 19)
Test Aquaria • Material: Glass or stainless steel • Size: Volume of 19 L (5 gal) or 30 x 60 x 30 cm • Fill volume: 15-30 L of solution	• Test chambers were 25-L stainless steel aquaria filled with 15 L of test water. (P. 12)
Type of Dilution System • Must provide reproducible supply of toxicant	• Continuous-flow diluter used and adjusted so that each test chamber received approximately six volume additions of test water every 24 hours. (P. 12)
Flow Rate • Consistent flow rate of 5-10 vol/24 hours • Meter systems calibrated before study and checked twice daily during test period	• Flow rate of approximately 6 vol/ 24 hours. Flow rates varied by no more than ±10% of the mean for the two replicates. (P. 11, 12) • Syringe pumps and rotameters were calibrated prior to the test. Diluter checked at least two times per day during the test and once at the end of the test. (P. 11, 12)
Biomass Loading Rate • Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C • Flow-through: ≤ 1 g/L/day	• Biomass loading rate: 0.032 g fish/L/day (P.10)
Photoperiod	• Yes. (P. 14)

Guideline Criteria	Reported Information
• 16 hours light, 8 hours dark	
Solvents • Not to exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests	• The use of solvents was not mentioned in the study report.

D. Test Design

Guideline Criteria	Reported Information
Range Finding Test • If LC_{50} >100 mg/L with 30 fish, then no definitive test is required.	• A range-finding test was not mentioned in the study report. There was an absence of mortality throughout test. LC_{50} value determined to be >117 mg/L (highest concentration tested). (P. 21)
Nominal Concentrations of Definitive Test • Control & 5 treatment levels • Dosage should be 60% of the next highest concentration • Concentrations should be in a geometric series	• Negative control and 5 nominal concentrations of 16, 26, 43, 72, and 120 mg/L. (P. 15) • Dosage was 60% of the next highest concentration.
Number of Test Organisms • Minimum 10/level • May be divided among containers	• Two replicates for control and each treatment level with 10 fish per replicate. (P. 21)
Test organisms randomly or impartially assigned to test vessels?	• Fish were impartially distributed one and two at a time to the test chambers until each contained 10 fish. (P. 11)
Biological observations made every 24 hours?	• Yes. (P. 15, 20)
Water Parameter Measurements • Temperature: Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1 °C • DO and pH: Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control	• Temperature measured continuously during the test ranged from 22 to 22.5°C. (P. 18) • DO and pH measured in the control and in one replicate of each dose at the beginning of test and every 24 h. (P. 18)
Chemical Analysis • Needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not steel or glass, or if flow-through system was used	• Analysis performed. (P. 12-13).

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes.
Percent Recovery of Chemical from Chemical Analysis	Yes.
Control Mortality • Not more than 10% control organisms may die or show abnormal behavior.	No mortality or abnormal behavior in the control groups. (P. 20)
Raw data included?	Yes.
Signs of toxicity (if any) were described?	No signs of toxicity observed.

Dose Response

Mortality

Nominal Concentration (mg ai/L)	Mean Measured Concentration (mg ai/L)	Number of Fish at Test Initiation	Number of Dead Fish				
			2 hour	24 hour	48 hour	72 hour	96 hour
Control	Control	10	0	0	0	0	0
16	14	10	0	0	0	0	0
26	24	10	0	0	0	0	0
43	40	10	0	0	0	0	0
72	68	10	0	0	0	0	0
120	117	10	0	0	0	0	0

Symptoms

Nominal Concentration (mg ai/L)	Mean Measured Concentration (mg ai/L)	Symptoms				
		5.5 hour	24 hour	48 hour	72 hour	96 hour
Control	Control	AN	AN	AN	AN	AN
16	14	AN	AN	AN	AN	AN

26	24	AN	AN	AN	AN	AN
43	40	AN	AN	AN	AN	AN
72	68	AN	AN	AN	AN	AN
120	117	AN	AN	AN	AN	AN

AN = appear normal (no symptoms of toxicity observed)

Statistical Results

Statistical Method:

Statistical calculation of the LC_{50} value was not performed due to the absence of mortality in any of the treatment groups during the test. Therefore, the 96-hour LC_{50} value was estimated to be greater than the highest concentration tested. The no mortality concentration and the NOEC were determined by visual interpretation of the mortality and observation data.

Results Synopsis:

96-hour LC50:	>117 mg/L
No Mortality Concentration:	117 mg/L
NOEC:	117 mg/L

13. VERIFICATION OF STATISTICAL RESULTS

Results were verified by visual inspection.

14. REVIEWER'S COMMENTS:

- No additional comments. Guideline deviations can be found in Section 9.

DATA EVALUATION RECORD
FISH ACUTE TOXICITY TEST, FRESHWATER AND MARINE
GUIDELINE OPPTS 850.1075

1. **CHEMICAL:** Aqueous Ammonia **PC Code No.: 005302**

2. **TEST MATERIAL:** Aqueous Ammonia **Purity:** 7.6% (total) ammonia
BUSAN 1215, Batch/Lot number 1 (a,b,&c)

3. **CITATION**

Author: Susan J. Palmer, B.S.
Timothy Z. Kendall, M.S.
Henry O. Krueger, Ph.D.
Title: Aqueous Ammonia Solution: A 96-Hour Flow-Through Acute Toxicity Test with the Rainbow Trout (*Oncorhynchus mykiss*)
Study Completion Date: November 8, 2003
Laboratory: Wildlife International, Ltd.
8598 Commerce Drive
Easton, Maryland 21601
Sponsor: Buckman Laboratories International
1256 N. McLean Blvd.
P.O. Box 80305
Memphis, Tennessee 38108-0305
Laboratory Report ID: Wildlife International, Ltd. Project Number: 210A-104
MRID No.: 464351-06

4. **REVIEWED BY:** Kathryn V .Montague, Biologist US EPA/AD/RASSB
Signature: Kathryn V. Montague **Date:** 10/17/05

5. **APPROVED BY:** Siroos Mostaghimi, Team Leader US EPA/AD/RASSB
Signature: Siroos Mostaghimi **Date:** 10/18/05

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: Rainbow Trout (*Oncorhynchus mykiss*)
Age of Test Organism: Juveniles
Definitive Test Duration: 96 Hours
Study Method: Flow-through
Type of Concentrations: Mean-measured

7. **CONCLUSIONS**

Results Synopsis:

96-hour LC50:	>126 mg/L
No Mortality Concentration:	126 mg/L
NOEC:	126 mg/L

Verified Results Synopsis:

Results were verified by visual inspection. There were no effects seen at any treatment level.

8. ADEQUACY OF THE STUDY

A. Classification: Acceptable (Core)

B. Rationale: No significant deviations from Guideline requirements.

C. Repairability: N/A

9. GUIDELINE DEVIATIONS:

The following guideline deviations were based on EPA OPPTS Guideline 850.1075:

- The mean wet weight of the test organism was 0.42 g and ranged from 0.34 to 0.56 g. The guideline recommends a mean weight of 0.5 to 5.0 g.
- The pH of the water in the test chambers ranged from 8.4 to 8.5. The guideline states a preferred pH range of 7.2 to 7.6.
- The hardness of the dilution water was measured at 132 mg/L as $CaCO_3$ at test initiation. The guideline states a preferred hardness range of 40 to 48 mg/L as $CaCO_3$.

10. SUBMISSION PURPOSE: Registration

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species • Preferred species: bluegill sunfish (*Lepomis macrochirus*) or rainbow trout (*Oncorhynchus mykiss*)	• Yes, rainbow trout (*Oncorhynchus mykiss*) (P.8).
Mean Weight • 0.5-5 g	• Mean wet weight was 0.42 g and ranged from 0.34 to 0.56 g. (P. 8)
Mean Standard Length	

Guideline Criteria	Reported Information
• Longest not > 2x shortest	• Mean total length was 4.0 cm and ranged from 3.7 to 4.3 cm. (P. 8)
Supplier	• Thomas Fish Company Anderson, California 96007 (P. 8)
All fish from same source?	• Yes. (P. 10)
All fish from the same year class?	• Yes. (P. 10)

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period • Minimum 14 days	• Yes, at least 14 days. (P. 11)
Wild caught organisms were quarantined for 7 days?	• Quarantine was not mentioned in the report. Fish were obtained from Thomas Fish Company.
Were there signs of disease or injury?	• The fish showed no signs of disease or stress. (P. 11)
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	• Not applicable. The fish showed no signs of disease or stress. (P. 11)
Feeding • No feeding during the study	• Rainbow trout were fed a commercially-prepared diet daily during the holding period. The fish were not fed for at least two days prior to the test or during the test. (P. 11)
Pretest Mortality • No more than 3% mortality 48 hours prior to testing	• Pretest mortality was not reported. The fish showed no signs of disease or stress. (P. 11)

C. Test System

Guideline Criteria	Reported Information
Source of dilution water • Soft reconstituted water or water from a natural source, not dechlorinated tap water	• Freshwater obtained from a well was used. (P. 11)
Does water support test animals without observable signs of stress?	• Percent mortality for the control was zero and the fish appeared normal. (P. 21)
Water Temperature • 12°C for cold water species	• Target test temperature during the study was 12 ± 1°C. Temperatures ranged from 11.4 to 12.4°C.

Guideline Criteria	Reported Information
• 17°C or 22°C for warm water species	(P. 15, 19)
pH • Prefer 7.2 to 7.6	• Ranged from 8.4 to 8.5. (P. 19)
Dissolved Oxygen • Static: ≥ 60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs • Flow-through: ≥ 60%	• Ranged from 8.4 to 9.2 mg/L (≥ 78% of saturation). (P. 15, 19)
Total Hardness • Prefer 40 to 48 mg/L as $CaCO_3$	• Hardness of dilution water measured at 132 mg/L as $CaCO_3$ at test initiation. (P. 20)
Test Aquaria • Material: Glass or stainless steel • Size: Volume of 19 L (5 gal) or 30 x 60 x 30 cm • Fill volume: 15-30 L of solution	• Test chambers were 25-L stainless steel aquaria filled with 15 L of test water. (P. 12)
Type of Dilution System • Must provide reproducible supply of toxicant	• Continuous-flow diluter used and adjusted so that each test chamber received approximately eight volume additions of test water every 24 hours. (P. 12)
Flow Rate • Consistent flow rate of 5-10 vol/24 hours • Meter systems calibrated before study and checked twice daily during test period	• Flow rate of approximately 8 vol/ 24 hours. Flow rates varied by no more than ±10% of the mean for the two replicates. (P. 12) • Syringe pumps and rotameters were calibrated prior to the test. Diluter checked at least two times per day during the test and once at the end of the test. (P. 12)
Biomass Loading Rate • Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C • Flow-through: ≤ 1 g/L/day	• Biomass loading rate: 0.033 g fish/L/day (P.10)
Photoperiod • 16 hours light, 8 hours dark	• Yes. (P. 14)
Solvents • Not to exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests	• The use of solvents was not mentioned in the study report.

D. Test Design

Guideline Criteria	Reported Information
Range Finding Test • If LC_{50} >100 mg/L with 30 fish, then no definitive test is required.	• A range-finding test was not mentioned in the study report. There was an absence of mortality throughout test. LC_{50} value determined to be >126 mg/L (highest concentration tested). (P. 22)
Nominal Concentrations of Definitive Test • Control & 5 treatment levels • Dosage should be 60% of the next highest concentration • Concentrations should be in a geometric series	• Negative control and 5 nominal concentrations of 16, 26, 43, 72, and 120 mg/L. (P. 15) • Dosage was 60% of the next highest concentration.
Number of Test Organisms • Minimum 10/level • May be divided among containers	• Two replicates for control and each treatment level with 10 fish per replicate. (P. 21)
Test organisms randomly or impartially assigned to test vessels?	• Fish were impartially distributed one and two at a time to the test chambers until each contained 10 fish. (P. 11)
Biological observations made every 24 hours?	• Yes. (P. 15, 21)
Water Parameter Measurements • Temperature: Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1 °C • DO and pH: Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control	• Temperature measured continuously during the test ranged from 12 to 12.5 °C. (P. 21) • DO and pH measured in the control and in one replicate of each dose at the beginning of test and every 24 h. (P. 21)
Chemical Analysis • Needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not steel or glass, or if flow-through system was used	• Analysis performed. (P. 12-14).

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes.
Percent Recovery of Chemical from Chemical Analysis	Yes.
Control Mortality • Not more than 10% control organisms may die or show abnormal behavior.	No mortality or abnormal behavior in the control groups. (P. 21)

Guideline Criteria	Reported Information
Raw data included?	Yes.
Signs of toxicity (if any) were described?	No signs of toxicity observed.

Dose Response

Mortality

Nominal Concentration (mg ai/L)	Mean Measured Concentration (mg ai/L)	Number of Fish at Test Initiation	Number of Dead Fish				
			5.5 hour	24 hour	48 hour	72 hour	96 hour
Control	Control	10	0	0	0	0	0
16	15	10	0	0	0	0	0
26	26	10	0	0	0	0	0
43	39	10	0	0	0	0	0
72	63	10	0	0	0	0	0
120	126	10	0	0	0	0	0

Symptoms

Nominal Concentration (mg ai/L)	Mean Measured Concentration (mg ai/L)	Symptoms				
		5.5 hour	24 hour	48 hour	72 hour	96 hour
Control	Control	AN	AN	AN	AN	AN
16	15	AN	AN	AN	AN	AN
26	26	AN	AN	AN	AN	AN
43	39	AN	AN	AN	AN	AN
72	63	AN	AN	AN	AN	AN
120	126	AN	AN	AN	AN	AN

AN = appear normal (no symptoms of toxicity observed)

Statistical Results

Statistical Method:

Statistical calculation of the LC_{50} values were not performed due to the absence of mortality in any of the treatment groups during the test. Therefore, the 96-hour LC_{50} value was estimated to be greater than the highest concentration tested. The no mortality concentration and the NOEC were determined by visual interpretation of the mortality and observation data.

Results Synopsis:

96-hour LC50:	>126 mg/L
No Mortality Concentration:	126 mg/L
NOEC:	126 mg/L

13. VERIFICATION OF STATISTICAL RESULTS

Results were verified by visual inspection.

14. REVIEWER'S COMMENTS:

- No additional comments. Guideline deviations can be found in Section 9.

DATA EVALUATION RECORD
AQUATIC INVERTEBRATE ACUTE TOXICITY TEST, FRESHWATER DAPHNIDS
GUIDELINE OPPTS 850.1010

1. **CHEMICAL:** Aqueous Ammonia **PC Code No.: 005302**

2. **TEST MATERIAL:** BUSAN 1215; Aqueous Ammonia **Purity:** 7.6% (total ammonia)
Batch/Lot number: 1 (a, b & c)

3. **CITATION**

Authors: Susan J. Palmer, B.S.
Timothy Z. Kendall, M.S.
Henry O. Krueger, Ph.D.
Title: Aqueous Ammonia Solution: A 48-Hour Flow-Through Acute Toxicity with the Cladoceran (*Daphnia magna*)
Study Completion Date: November 5, 2004
Report Date: November 5, 2004
Laboratory: Wildlife International, Ltd.
8598 Commerce Drive
Easton, Maryland 21601
Sponsor: Buckman Laboratories International
1256 N. McLean Blvd.
P.O. Box 80305
Memphis, Tennessee 38108-0305
Laboratory Report ID: 210A-102
MRID No.: 464351-07

4. **REVIEWED BY:** Kathryn V. Montague, Biologist US EPA/AD/RASSB
Signature: Kathryn V. Montague **Date:** 10/17/05

5. **APPROVED BY:** Siroos Mostaghimi, Team Leader US EPA/AD/RASSB
Signature: Siroos Mostaghimi **Date:** 10/18/05

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: Cladoceran (*Daphnia magna*)
Age of Test Organism: neonates; less than 24 hours old
Definitive Test Duration: 48- hours
Study Method: Flow-through
Type of Concentrations: Mean-measured

7. CONCLUSIONS

Results Synopsis:

48-hour EC_{50}:	>131 mg/L
No Mortality Concentration:	131 mg/L
NOEC:	131 mg/L

Verified Results Synopsis:

Results were verified by visual inspection. There were no effects observed at any treatment level.

8. ADEQUACY OF THE STUDY

A. Classification: Acceptable (Core)

B. Rationale: No significant deviations from Guideline requirements

C. Repairability: N/A

9. GUIDELINE DEVIATIONS:

The following guideline deviations were based on EPA OPPTS Guideline 850.1010:

- The study did not provide the approximate sizes of the daphnids.
- The study did not provide daphnid mortality rate prior to testing; however, the study does indicate that adults did not show signs of disease or stress during 14-day holding period.
- The testing pH ranged from 8.3 to 8.4. The preferred range, stated in guideline 850.1010, is 7.2 to 7.6.
- The study did not mention a range-finding test.

10. SUBMISSION PURPOSE: Registration

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species • *Daphnia magna* • *D. pulex*	• *Daphnia magna* (p. 8)

/3-

Guideline Criteria	Reported Information
Life Stage • Daphnids: 1st instar (<24 h) • Amphipods, stoneflies, and mayflies: 2nd instar • Midges: 2nd & 3th instar	• Daphnid neonates were less <24 hours old. (p. 10)
All organisms from same source?	• Cultures maintained by Wildlife International, Ltd. (p. 10)
Organisms approximately same size and age?	• Approximate sizes not provided
Signs of disease or injury?	• No, adult daphnids used to produce the neonates did not show sign of disease or stress during a 14 day holding period prior to neonate collection. (p.10)
Acclimation Period Minimum 7 days	• 14 days (p. 10)
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	• Not treated for disease
Feeding No feeding during the study.	• No feeding during the study. (p.11)
Pretest Mortality No more than 3% mortality 48 hours prior to testing.	• Mortality rate prior to testing not provided

B. Test System

Guideline Criteria	Reported Information
Source of dilution water • Soft reconstituted water or water from a natural source, **not** dechlorinated tap water.	• Water obtained from well on-site. (p.11)
Does water support test animals without observable signs of stress?	• Information not provided; however, culture and test water were from same source and cultured adult daphnids did not show any sign of stress or disease.
Photoperiod • 16-hr light and 8-hr dark with 15- to 30-minute transition period.	• Yes, with 30- minute transition (p. 14)
Test Aquaria • Material: Glass or stainless steel. • Size: 250 ml (daphnids and midges) or 3.9 L (1 gal). • Fill volume: 200 ml (daphnids and midges) or 2-3 L.	• Yes, each test compartment was 300 ml glass beaker suspended in a stainless steel aquaria filled with 22 L. (p. 12)
Type of Dilution System • Must provide reproducible supply of toxicant.	• Continuous-flow diluter used and adjusted so that each test chamber received at least five volume

Guideline Criteria	Reported Information
	additions of test water every 24 hours. (p. 11 & 12)
Water Temperature • Daphnia: 20°C • Amphipods and mayflies: 17°C • Midges and mayflies: 22°C • Stoneflies: 12°C	• 20 ± 1°C (p. 15)
Dissolved Oxygen • Static: ≥ 60% during 1st 48 h and ≥ 40% during 2nd 48 h • Flow-through: ≥ 60%.	• Oxygen concentrations were ≥8.4 mg/L (≥93% of saturation) (p. 15)
pH • Prefer 7.2 to 7.6.	• pH ranged from 8.3 to 8.4 (p. 15)
Total Hardness • Prefer 40 to 48 mg/L as $CaCO_3$.	• $CaCO_3$ at Day 0 = 116 mg/L (p. 20)
Flow Rate • Consistent flow rate of 5-10 vol/24 hours • Meter systems calibrated before study and checked twice daily during test period.	• Flow rate of approximately 5 vol/ 24 hours. Flow rates varied by no more than ±10% of the mean for the two replicates. (P. 11-12) • Syringe pumps were calibrated prior to the test. Diluter checked visually at least two times per day during the test and once at the end of the test. (P. 11 & 12)
Biomass Loading Rate • Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C • Flow-through: ≤ 1 g/L/day.	• Biomass loading rate not provided.
Solvents • Not to exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests.	• The use of solvents was not mentioned in the Study Report.

C. Test Design

Guideline Criteria	Reported Information
Range Finding Test • If LC_{50} >100 mg/L, then no definitive test is required.	• A range-finding test was not mentioned in the Study Report.
Nominal Concentrations of Definitive Test • Control & 5 treatment levels • A geometric series with each concentration being at least 60% of the next higher one.	• Negative control and 5 nominal concentrations of 16, 26, 43, 72, and 120 mg/L. (P. 8 & 15) • Dosage was 60% of the next highest concentration.
Number of Test Organisms • Minimum 20/level, may be divided among containers.	• 10 per replicate and 2 replicates per dose level; 20 per level. (p. 21)
Test organisms randomly or impartially assigned to test vessels?	• Daphnids were indiscriminately transferred one and two at a time to the test chambers until each contained 10 daphnids. (p. 11)
Water Parameter Measurements • Temperature: Measured continuously or, if water baths are used, every 6 h, may not vary > 1°C. • DO and pH: Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control.	• Temperature measured in each test chamber at the beginning and end of test, and continuously in one negative control test chamber (p.14). • DO and pH measured in alternating replicate test chambers of each treatment and control group at beginning and end of test and at 24 hour intervals during test (p. 14)
Chemical Analysis • Needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not steel or glass, or if flow-through system was used	• Samples were collected from altemating test chambers in treatment and control at test initiation and termination to measure concentrations of test substance (p.12)

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	• Yes, but the GLP states that the title of the study is "Aqueous Ammonia Solution: A 96-Hour Flow-Through Acute Toxicity Test with the Rainbow Trout (*Oncorhynchus mykiss*)" and that the study completion date is November 8, 2004.
Control Mortality • Static: ≤10%	• No mortality or abnormal behavior in the control

Guideline Criteria	Reported Information
• Flow-through: ≤5%	groups. (p. 21)
Percent Recovery of Chemical	• Yes; ranged from 88%-109% (p. 18)
Raw data included?	• Yes (Appendix p. 18 and on)

Dose Response

Mortality

Nominal Test Concentration (mg/L)	Mean Measured Test Concentration (mg/L)	Number of Organisms	Cumulative Number Dead		
			Hour of Study		
			2	24	48
Control	Negative Control	20	0	0	0
16	14	20	0	0	0
26	23	20	0	0	0
43	39	20	0	0	0
72	73	20	0	0	0
120	131	20	0	0	0

Symptoms

Nominal Test Concentration (mg/L)	Mean Measured Test Concentration (mg/L)	Symptoms		
		2 hour	24 hour	48 hour
Control	Negative Control	AN	AN	AN
16	14	AN	AN	AN
26	23	AN	AN	AN
43	39	AN	AN	AN
72	73	AN	AN	AN
120	131	AN	AN	AN

AN = appear normal (no symptoms of toxicity observed)

Statistical Results

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Statistical Method:

Statistical calculation of the EC_{50} values were not performed due to the absence of mortality in any of the treatment groups during the test. Therefore, the 48-hour EC_{50} values were estimated to be greater than the highest concentration tested. The no mortality concentration and the NOEC were determined by visual interpretation of the mortality and observation data.

Results Synopsis:

48-hour EC_{50}:	>131 mg/L
No Mortality Concentration:	131 mg/L
NOEC:	131 mg/L

13. VERIFICATION OF STATISTICAL RESULTS

Results were verified by visual inspection as there were no effects observed at any treatment level.

14. REVIEWER'S COMMENTS:

- The GLP states that the title of the study is: :Aqueous Ammonia Solution: A 96-Hour Flow-Through Acute Toxicity Test with the Rainbow Trout (*Oncorhynchus mykiss*)" and lists the study completion date as November 8, 2004. Versar is assuming that this GLP statement was accidently switched with another study.

MAY 16 2005

Mr. Carl F. Watson, Ph. D.
Sr. Regulatory Toxicologist
Buckman Laboratories, Inc.
1256 N. McLean Blv.
Memphis, TN 38108

Dear Mr. Watson:

Subject: **EPA File Symbol Numbers 1448-UGG Busan 1215 and 1448-UGE BCMW**
Application Dated: December 21, 2004
EPA Receipt Date: December 23, 2004

The Agency has conducted a partial review of the data submitted in support of file symbol numbers 1448-UGG and 1448-UGE. We will notify you when additional reviews are completed.

Proposed Request:

- Application for new product registration

Data Reviews:

I. ***Acute Toxicity Review for 1448-UGG Busan 1215:***

Acute Toxicity:

The acute toxicity data submitted is acceptable. The current acute toxicity database regulatory status for the subject product is summarized in the table below.

Data Requirement	Means of Support	Status/ Tox. Category
Acute Oral Toxicity	MRID #464351-08	Acceptable/Tox category IV
Acute Dermal Tox.	MRID #464351-09	Acceptable/Tox category IV
Acute Inhalation Tox.	MRID #464351-10	Acceptable/Tox category IV
Primary Eye Irritation	MRID #464351-11	Acceptable/ category IV
Primary Skin Irritation	MRID #464351-12	Acceptable/Tox category IV
Dermal Sensitization	MRID #464351-13	Acceptable/Non-Sensitizer

CONCURRENCES

SYMBOL							
SURNAME							
DATE							7-3-05

Labeling Comments:

a. The signal word is "Caution"
b. Due to the acute toxicity profile (all category IV and nonsensitizer), no precautionary labeling is required.

Acute Toxicity Review for 1448-UGE/ BCME:

Acute Toxicity:

The acute toxicity data submitted is acceptable. The current acute toxicity database regulatory status for the subject product is summarized in the table below.

Data Requirement	Means of Support	Status/ Tox. Category
Acute Oral Toxicity	MRID #464351-08	Cited/Tox category IV
Acute Dermal Tox.	MRID #464351-09	Cited/Tox category IV
Acute Inhalation Tox.	MRID #464351-10	CitedTox category IV
Primary Eye Irritation	MRID #464351-11	Cited/ category IV
Primary Skin Irritation	MRID #464351-12	Cited/Tox category IV
Dermal Sensitization	MRID #464351-13	Cited/Non-Sensitizer

Labeling Comments:

a. The signal word is "Caution"
b. Due to the acute toxicity profile (all category IV and nonsensitizer), no precautionary labeling is required.

Product Chemistry Review 1448-UGE BCMW:

1. The requirements for PR Notice 91-2 are satisfied. The nominal concentration of the active ingredient, ammonia, given in the Basic CSF agreed with the percentage declared on the label.

2. The upper and lower certified limits for the active and inert ingredients are acceptable with the exception of the [redacted] You must base all certified limits on the nominal concentration (N) of each ingredient. The (N) value for the [redacted]

3. All other ingredients utilized are approved for use in pesticide formulations.

4. The end-use product (EP) Busan1215 is a 100% repack of the proposed manufacturing-use (MUP) BCMW.

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5. The Product Chemistry Data submitted is complete and consistent with the chemical and physical characteristic of an aqueous ammonia solution.

6. A 28 day Accelerated Storage Stability Study was completed involving **Busan 1215**. No evidence of active ingredient loss and product package (opaque HDPE) degradation was observed. You must complete a 1-year Storage Stability and Corrosion Characteristic study covering this product.

7. All other elements of this submission and the two Basic CFSs for **BCMW** and **Busan** 1215 are acceptable.

Other Comments:

For detailed information and considerations, please refer to the enclosed EPA/AD Product Science Branch review (product chemistry, acute toxicity) reviews.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,

Vemla Nobel
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosures: Product Chemistry, Acute Toxicity Reviews

BUCKMAN LABORATORIES INTERNATIONAL, INC.

1256 NORTH McLEAN BLVD.
MEMPHIS, TN 38108-1241 U.S.A.
TELEPHONE (901) 278-0330
FAX (901) 276-5343
www.buckman.com
e-mail: knetix@buckman.com

Via Federal Express

December 21, 2004

US Environmental Protection Agency
Document Processing Desk (New Registration)
Office of Pesticide Programs, Antimicrobial Division (PM 31)
Crystal Mall 2, Room 266A
1801 S. Bell Street
Arlington, VA 22202

Re: BCMW / BUSAN 1215 - Application for a New Pesticides

Enclosed please find an application for a new product registration for Buckman Laboratories, Inc. product: BCMW - MUP and BUSAN 1215 - EUP). Enclosed you will find the following information to support this application:

- Two (2) Applications under PRIA, one for each Pesticide Registration (MUP/EUP)
- Three (3) copies of each product Confidential Statement of Formula
- Two (2) Certifications with Respect to Citation of Data, one for each product.
- Two (2) Data Requirement Listings (Data Matrix)
- One (1) copy of Data Waiver
- Five (5) Copies of the Proposed Labeling for each product.
- Three (3) Copies of all Required Toxicology Studies

If you have any questions or require any additional information regarding this application, please feel free to contact me.

Sincerely,
BUCKMAN LABORATORIES INTERNATIONAL, INC.

Carl F. Watson, Ph.D.
Sr. Regulatory Toxicologist

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter: Buckman Laboratories, Inc.
   1256 N. McLean Blvd.
   Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

   Data to Support New Registration:
   Busan 1215 – End Use Product

3. Transmittal Date: 21 December 2004

4. List of Submitted Studies:

   Vol. 1: Product Chemistry for BCMW:
   Physical/Chemical Properties
   Buckman Laboratories, Inc.
   Report Date: December 20, 2004

   Guideline Number: Series 63 (OPPTS 830 Series)

MRID No: _____

Company Official: Carl F. Watson, Ph.D.

Signature: Carl F. Watson

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter: Buckman Laboratories, Inc.
1256 N. McLean Blvd.
Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

Data to Support New Registrations:
BCMW – Manufacturing Use Product
Busan 1215 – End Use Product

3. Transmittal Date: 21 December 2004

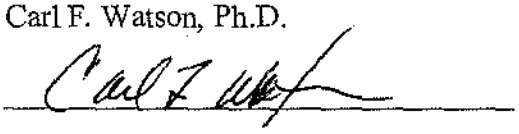
4. List of Submitted Studies:

Vol. 1: Accelerated Storage Stability Study
Product Safety Laboratories
Report Date: October 11, 2004

Guideline Number: 63-13 (OPPTS 830.6313)

MRID No: _____

Company Official: Carl F. Watson, Ph.D.

Signature: 

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter: Buckman Laboratories, Inc.
1256 N. McLean Blvd.
Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

Data to Support New Registrations:
BCMW – Manufacturing Use Product
Busan 1215 – End Use Product

3. Transmittal Date: 21 December 2004

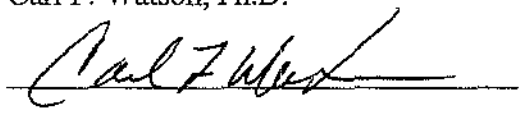
4. List of Submitted Studies:

Vol. 1: Aqueous Ammonia Solution: A 96-Hour Flow-through Acute Toxicity Test with the Bluegill (*Lepomis macrochirus*)
Wildlife International, Ltd
Report Date: December 2, 2004

Guideline Number: 72-1a (OPPTS 850.1075)

MRID No: _____

Company Official: Carl F. Watson, Ph.D.

Signature: 

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

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TRANSMITTAL DOCUMENT

1. Name and Address of Submitter: Buckman Laboratories, Inc.
   1256 N. McLean Blvd.
   Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

   Data to Support New Registrations:
   BCMW – Manufacturing Use Product
   Busan 1215 – End Use Product

3. Transmittal Date: 21 December 2004

4. List of Submitted Studies:

   Vol. 1: Aqueous Ammonia Solution: A 96-Hour Flow-through Acute Toxicity Test with the Rainbow Trout (*Oncorhynchus mykiss*)
   Wildlife International, Ltd
   Report Date: November 8, 2004

   Guideline Number: 72-1b (OPPTS 850.1075)

MRID No: _____

Company Official: Carl F. Watson, Ph.D.

Signature: Carl F Watson

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

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TRANSMITTAL DOCUMENT

1. Name and Address of Submitter: Buckman Laboratories, Inc.
   1256 N. McLean Blvd.
   Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

   Data to Support New Registrations:
   BCMW – Manufacturing Use Product
   Busan 1215 – End Use Product

3. Transmittal Date: 21 December 2004

4. List of Submitted Studies:

   Vol. 1: Aqueous Ammonia Solution: A 48-Hour Flow-through Acute Toxicity Test with the Cladoceran (*Daphnia magna*)
   Wildlife International, Ltd
   Report Date: November 5, 2004

   Guideline Number: 72-2a (OPPTS 850.1010)

MRID No: _____

Company Official: Carl F. Watson, Ph.D.

Signature: Carl F Watson

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

TRANSMITTAL DOCUMENT

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   1256 N. McLean Blvd.
   Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

   Data to Support New Registrations:
   BCMW – Manufacturing Use Product
   Busan 1215 – End Use Product

3. Transmittal Date: 21 December 2004

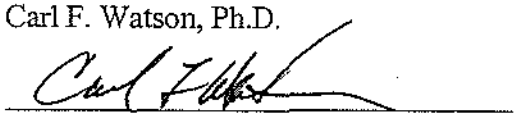
4. List of Submitted Studies:

   Vol. 1: Dermal Sensitization Study in Guinea Pigs (Buehler Method)
   Product Safety Laboratories
   Report Date: October 7, 2004

   Guideline Number: 81-6 (OPPTS 870.2600)

MRID No: _____

Company Official: Carl F. Watson, Ph.D.

Signature: 

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

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Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

- [x] **Registration**
- [ ] **Amendment**
- [ ] **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
1448- UGG	Velma Noble	☐ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
BUSAN 1215	34	

5. Name and Address of Applicant *(Include ZIP Code)*

Buckman Laboratories, Inc.
1256 N. McLean Blvd
Memphis, TN 38108

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- ☐ Amendment - Explain below.
- ☐ Resubmission in response to Agency letter dated _____
- ☐ Notification - Explain below.
- ☐ Final printed labels in repsonse to Agency letter dated _____
- ☐ "Me Too" Application.
- ☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

PRIA Category: EPA No. A50, CR No. 48 - Action: New use, non-food, indoor FIFRA sec. 2(mm) uses
Reg. Fee: NA (fee covered under BCMW submission)
New Registration: BCMW - Manufacture-Use-Only / BUSAN 1215 - End-Use-Product
New Use for PC Code 5302
Contact: cfwatson@buckman.com; Fax (901) 272-6256

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☑ Metal ☑ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☑ Container	55 & 250 gal, Bulk	☑

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☑ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carl Watson	Sr. Regulatory Toxicologist	(901) 272-6226

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	5. Date
Carl F. Watson	Sr. Regulatory Toxicologist	21 December 2004

4. Typed Name: Carl F. Watson, Ph.D.

12/6

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the Instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Buckman Laboratories, Inc., 1256 N. McLean Blvd, Memphis, TN 38108 (901) 272-6228	EPA Registration Number/File Symbol 1448-_____ (New Registration)
Active Ingredient(s) and/or representative test compound(s) Ammonia (PC Code 5302)	Date December 21, 2004
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Industrial, Aquatic, Indoor, Non-food	Product Name BUSAN 1215

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Carl F. Watson	12/21/04	Carl F. Watson; Ph.D., Sr. Regulatory Toxicologist

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: December 20, 2004	EPA Reg No./File Symbol 1448-___	Page 1 of 1
Applicant's/Registrant's Name & Address: Buckman Laboratories International, Inc. 1256 North McLean Blvd. Memphis, TN 38108	Product **BUSAN 1215**	

Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Series 61	All Data Requirements	N/A	Buckman Laboratories, Inc.	OWN	Reg. App. in review
Product Chemistry Series 62	All Data Requirements	N/A	Buckman Laboratories, Inc.	OWN	Reg. App. in review
Product Chemistry Series 63	All Data Requirements	N/A	Buckman Laboratories, Inc.	OWN	Reg. App. in review
ECOLOGICAL EFFECTS		N/A			
850.2100 (71-1)	Acute Avian Oral – Quail/Duck	N/A	Buckman Laboratories, Inc.	OWN	Reg. App. in review
850.1075 (72-1a)	Fish Toxicity Rainbow Bluegill	N/A	Buckman Laboratories, Inc.	OWN	Reg. App. in review
850.1075 (72-1c)	Fish Toxicity Rainbow Trout	N/A	Buckman Laboratories, Inc.	OWN	Reg. App. in review
850.1010 (72-2a)	Invertebrate Toxicity	N/A	Buckman Laboratories, Inc.	OWN	See BCMW, Reg. App. in review
TOXICOLOGY					
870.1100 (81-1)	Acute Oral Toxicity – Rat	N/A	Buckman Laboratories, Inc.	OWN	Reg. App. in review
870.1200 (81-2)	Acute Dermal Toxicity – Rabbit/Rat	N/A	Buckman Laboratories, Inc.	OWN	Reg. App. in review
870.1300 (81-3)	Acute Inhalation Toxicity – Rat	N/A	Buckman Laboratories, Inc.	OWN	Reg. App. in review
870.2400 (81-4)	Primary Eye Irritation – Rabbit	N/A	Buckman Laboratories, Inc.	OWN	Reg. App. in review
870.2500 (81-5)	Primary Dermal Irritation – Rabbit	N/A	Buckman Laboratories, Inc.	OWN	Reg. App. in review
870.2600 (81-6)	Dermal Sensitization – Guinea Pig	N/A	Buckman Laboratories, Inc.	OWN	Reg. App. in review

Signature	Name and Title	Date
Carl Watson	Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	12/20/04

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: December 20, 2004	EPA Reg No./File Symbol 1448-___	Page 1 of 1
Applicant's/Registrant's Name & Address: Buckman Laboratories International, Inc. 1256 North McLean Blvd. Memphis, TN 38108	Product **BUSAN** 1215	

Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
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			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review
			Buckman Laboratories, Inc.	OWN	Registration App. in review

Signature	Name and Title	Date
Carl F. Watson	Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	12/20/04

BUSAN 1215

BUSAN is a registered trademark.

A microbiocide for controlling algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products.

ACTIVE INGREDIENT(S)	
Ammonia (total)	7.59%
INERT INGREDIENTS	92.41%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
If in Eyes	- Hold eye open and rinse slowly and gently with water for 15-20 minutes. - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. - Call a poison control center or doctor for further treatment advice.
If on Skin, Clothes	- Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for treatment advice.
If Swallowed	- Call poison control center or doctor immediately for treatment advice. - Have person sip a glass of water, if able to swallow. - Do not induce vomiting unless told to do so by the poison control center or doctor. - Do not give anything by mouth to an unconscious person.
If Inhaled	- Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. - Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 901-278-0330 or 1-800-BUCKMAN for emergency medical treatment information.	

Precautionary Statements

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PULP AND PAPER MILLS: This product is applied in conjunction with sodium hypochlorite (12.5%) to form monochloramine, a slower acting less aggressive oxidizing microbicide. The products are added to dilution water to achieve a minimum molar ratio of 1.5 : 1 of ammonia to oxidant, and this ratio is obtained by combining 0.6 fluid ounces of Busan 1255 to 1 fluid ounce of sodium hypochlorite (12.5%). To ensure both handling safety and effectiveness, the monochloramine solution should be generated and fed into the treatment water systems through a proper chemical feed skid only by a trained Buckman representative. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained. The frequency of feeding and the duration of the treatment will depend on the severity of the problem.

If chloramine is detected in the effluent, it can be neutralized by the addition of sodium meta bisulfite until the chloramine is no longer detected.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a dry place. Leaking or damaged drums should be placed in overpack drums for disposal. Spills should be absorbed in sawdust or sand and disposed of in a sanitary landfill. Keep container closed when not in use.

PESTICIDE DISPOSAL: Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional office for guidance. Clean equipment and/or dispose of equipment wash water in a manner to avoid contamination of water resources.

CONTAINER DISPOSAL

PLASTIC: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

METAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Manufactured by

Buckman Laboratories, Inc.

1256 North McLean Blvd.

Memphis, Tennessee 38108, USA

(901) 278-0330 or 1-800-BUCKMAN

EPA Est. No.	1448-TN-1
EPA Reg. No.	1448-
Product Weight	9.59 lbs/gal 1.15kg/l

Net contents are marked on the container.

HMIS / NPCA Ratings

Health	Flammability	Reactivity
1	1	0

Last Revision 12/21/2004

TRANSMITTAL DOCUMENT

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   1256 N. McLean Blvd.
   Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

   Data to Support New Registrations:
   BCMW – Manufacturing Use Product
   Busan 1215 – End Use Product

3. Transmittal Date: 21 December 2004

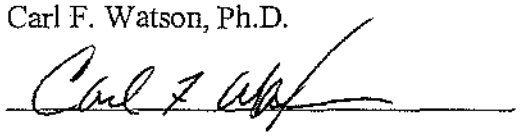
4. List of Submitted Studies:

   Vol. 1: Acute Oral Toxicity Up and Down Procedure in Rats
   Product Safety Laboratories
   Report Date: October 7, 2004

   Guideline Number: 81-1 (OPPTS 870.1100)

MRID No: _____

Company Official: Carl F. Watson, Ph.D.

Signature: 

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

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   1256 N. McLean Blvd.
   Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

   Data to Support New Registrations:
   BCMW – Manufacturing Use Product
   Busan 1215 – End Use Product

3. Transmittal Date: 21 December 2004

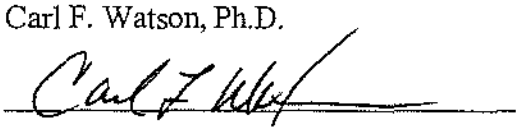
4. List of Submitted Studies:

   Vol. 1: Acute Dermal Toxicity Study in Rats – Limit Test
   Product Safety Laboratories
   Report Date: October 7, 2004

   Guideline Number: 81-2 (OPPTS 870.1200)

MRID No: _____

Company Official: Carl F. Watson, Ph.D.

Signature: 

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

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TRANSMITTAL DOCUMENT

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1256 N. McLean Blvd.
Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

Data to Support New Registrations:
BCMW – Manufacturing Use Product
Busan 1215 – End Use Product

3. Transmittal Date: 21 December 2004

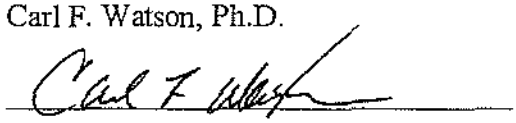
4. List of Submitted Studies:

Vol. 1: Acute Inhalation Toxicity Study in Rats – Limit Test
Product Safety Laboratories
Report Date: October 7, 2004

Guideline Number: 81-3 (OPPTS 870.1300)

MRID No: _____

Company Official: Carl F. Watson, Ph.D.

Signature: 

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Company Contact: Carl F. Watson, Ph.D.

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   1256 N. McLean Blvd.
   Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

   Data to Support New Registrations:
   BCMW – Manufacturing Use Product
   Busan 1215 – End Use Product

3. Transmittal Date: 21 December 2004

4. List of Submitted Studies:

   Vol. 1: Primary Eye Irritation Study in Rabbits
   Product Safety Laboratories
   Report Date: October 7, 2004

   Guideline Number: 81-4 (OPPTS 870.2400)

MRID No: _____

Company Official: Carl F. Watson, Ph.D.

Signature: _____

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

159

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1. Name and Address of Submitter: Buckman Laboratories, Inc.
1256 N. McLean Blvd.
Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

Data to Support New Registrations:
BCMW – Manufacturing Use Product
Busan 1215 – End Use Product

3. Transmittal Date: 21 December 2004

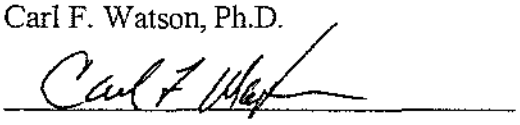
4. List of Submitted Studies:

Vol. 1: Primary Skin Irritation Study in Rabbits
Product Safety Laboratories
Report Date: October 7, 2004

Guideline Number: 81-5 (OPPTS 870.2500)

MRID No: _____

Company Official: Carl F. Watson, Ph.D.

Signature: 

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

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1256 N. McLean Blvd.
Memphis, TN 38108

2. Regulatory Action in Support of Which this Package is Submitted:

Data to Support New Registration:
BCMW – Manufacturing Use Product
Busan 1215 – End Use Product

3. Transmittal Date: 21 December 2004

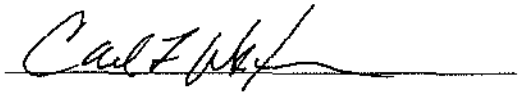
4. List of Submitted Studies:

Vol. 1: Supplemental Report: Mammalian Toxicology and Environmental Fate and Effects
Buckman Laboratories, Inc.
Report Date: December 20, 2004

Guideline Number: Waiver Requests

MRID No: _____

Company Official: Carl F. Watson, Ph.D.

Signature: 

Company Name: Buckman Laboratories, Inc.

Company Contact: Carl F. Watson, Ph.D.

Phone: (901) 272-6228

FOR OFFICIAL USE ONLY

FILE SYMBOL
1448-UGG
REGISTRATION NO.

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
12/23/04		

Do Not Write Comments, Formula, or Parts of Formula on This Envelope

NOTE

It shall be unlawful-----for any person to use for his own advantage or to reveal, other than to the Secretary ,or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena,or to physicians,and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

Confidential Statement of Formula may be entitled to confidential treatment